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C O N T E N T S

P R O C E E D I N G S

DR. MONSEES: We want to get started so that we can finish. You had an easy day yesterday because you listened to didactic sessions and you didn't have to talk that whole time. But we hope to finish by 3 o'clock, 2:45, if we are lucky, today so that people can be out of here.

Here is how we are going to proceed. Of course, we could get sidetracked but we will try and avoid that as much as possible. We are going to start out revising personnel issues, particularly physician personnel issues at the request of Dr. Winchester. Anybody else that has any additional personnel issues regarding physicians, technologists or physicists, we need to hear those this morning.

Then we are going to move to the questions, the NMQAAC questions. There are ten of them but some of them kind of can be worked on together. That is, I think, going to help us to look at other procedures such as cyst aspiration, galactography and breast needle localization so that those times slots, I think, won't be designated solely as indicated on the agenda.

So we will move things around. Then we are going to hear about states as certifiers before we finish up the day.

Stereotactic Core Biopsy--Personnel (Continued)

DR. MONSEES: Dr. Winchester, I am going to throw the ball into your court, now, because you raised the question of other personnel issues. Why don't you go for it.

DR. WINCHESTER: Thank you very much. Yesterday, we spent a lot of time talking about how to increase the skills of the surgeon practicing in an independent setting. There was a lot of good discussion about how we could arrive at that goal. In my testimony yesterday, I brought before you some broad-based surgical input which included the surgeon's assessment of the radiology model practicing in an independent setting.

We didn't really have much time to talk about that yesterday. Technically, you can say that I shouldn't be critiquing something that I developed with Dr. Bassett and others but this, in fact, is a representation of some of the input I have had from other surgeons.

I have also talked to a couple of the radiologists on the panel, the advisory committee, knowing full well what they were going to say and that was I asked them to describe how they practice, themselves, in an independent setting. It was obvious to me the way they practice in an independent setting was exemplary and was in the patient's best

interest.

They understood breast disease as well as surgeons understood breast disease because they attended regular conferences on breast cancer. They did breast physical examinations in their centers so that the woman would not come into an independent setting of radiology and have a mammogram or diagnostic workup, imaging workup, without a breast physical examination.

So it was clear to me that those here, at least, who are doing this independently, are doing it very, very well. My concern is that the document that we have put forth doesn't encompass the things that are, in fact, being done by the best radiologists in this country. If the radiologists who are doing it the best believe that that is the standard of care in this country, then I think we need to suggest some modifications to the radiology requirements practicing in an independent setting.

I don't think it is exactly fair for me to try and set those bullet points. I think what I might suggest is that either Dr. Sickles or Dr. Mendelson, or both, might describe to the advisory committee--or others on the advisory committee as well--what they believe the standard of care for a radiologist practicing in an independent setting should be.

If that is the case, and there is consensus on that point, then I think we ought to suggest some revisions to this document.

Dr. Sickles?

DR. SICKLES: Several aspects of any physician practicing in an independent setting have to be worked in, let's say. Radiologists come to the practice of stereotactic breast biopsy with certain strengths, traditional strengths, imaging strengths. Surgeons come to the procedure practicing independently with other strengths, clinical strengths, in terms of a clinical breast exam and the ability to follow patients over the course of the entire illness.

So I think if we are to define programmatically in a document like what has been produced by the ACS and ACR what individuals should do, we should be emphasizing, in the radiologist's part, areas where we should be sure that they are proficient where maybe they haven't had that necessary training.

Similarly, for surgeons, we should be defining areas in imaging where they need it. That is why, in the surgeons' program, they are proficient for a certain number of mammogram exams to be looked at in consultation. Areas where a radiologist might be called into question would be,

for example, clinical exam.

So I think anybody doing a stereotactic breast biopsy should make sure that the patient has had a competent clinical breast exam before the procedure is done. That doesn't, necessarily, mean, by the way that the radiologist has to do it. The radiologist could do it himself, or herself, and many radiologists such as those in my practice will do that because we know how to do them. We have been trained to do them many, many years ago and we train each other how to do because we have learned.

Radiologists who don't have that training could easily obtain it with preceptorships by surgeons or by other means. I am not aware that there are courses where one goes to learn how to do a breast clinical exam. I don't think there are such courses but there certainly would be local expertise where they could pick this up.

Another easy way to do it would simply be to have any patient who is having a stereotactic breast biopsy have a consultation with somebody else who is competent in doing it if the radiologist felt that he or she didn't know how to do it. I am sure that is another perfectly acceptable way to go about it.

How do radiologists learn about management of breast disease? There are a variety of ways in which they

could achieve this. Most of them, probably all of them, already know how to do it, those who are doing these types of procedures in an independent setting. But, certainly, they can achieve this by attending local tumor-board conferences, conferences that they may have or can arrange with their local surgeons to discuss the management of patients, either that they have already done stereotactic biopsies on or patients who are known to have breast cancer.

We do this in our practice on a routine basis almost every week. I don't know that it needs to be done every week. I think that may be onerous for radiologists in low-volume practices--but some type of provision like this I think should be there.

Apart from those two--I listened carefully to what the comments were yesterday. I think those were the major areas of concern. Ellen and Pete and Laura, you might have comments as well.

DR. MONSEES: Do I have a volunteer here?

DR. MENDELSON: I practice much in the same way that Dr. Sickles does. Just in the history of the development of how we care for patients with breast disease, I think we can hark back to how interventional radiology developed and this is as an outcome of that.

If there is any area in radiology, in diagnostic radiology, where you have a relationship with a patient, it is in the area of interventional regulatory. In GI work, you can consider a patient relationship but it is transient. Here, in interventions, biliary interventions or where you are caring for cancer patients and helping in their treatment and in assessing where they are in the control of their disease, I think that there is a bonding.

I know Dr. Winchester and some of the other speakers yesterday alluded to patient bonding and how that, in the stereotyped picture of a radiologist, is missing in diagnostic radiologists and their assessment and evaluations and working with patients in breast centers.

I think this has changed and is in the process of change. We talked a lot yesterday about education. In the many meetings, and we find them all very well subscribed for breast disease, perhaps because of the regulations and the need to have the CME credits. But there are many panel discussions about how one manages patients, whose responsibility it is if you do interventional procedures to communicate the results to the patients.

I feel it is the responsibility of whoever does the procedure to be in touch with that patient, either ask the patient to come to see you and discuss it in person or,

in some instances, on the phone and to work very closely with the physician team, the surgeon, the obstetrician/gynecologist, the family practitioners who are calling on you for your imaging expertise.

That responsibility, I think, has been assumed. Along with that, as we have more hands-on contact with patients, either doing procedures or, for example, in doing breast sonograms--and yesterday, the importance of breast ultrasound became evident. We use it much more now for imaging assessment as well as for guidance of procedures as a very effective way to guide these procedures.

During the process of breast ultrasound, if the radiologist is doing the study him or herself, then they should always go in and evaluate the sonograms personally. It is an opportune time to correlate mammographic findings, the clinical history, the possibility of a finding on self examination, and more and more women will tell you about that, at the time that you do the sonogram.

So there is a good moment to integrate the clinical findings with the imaging findings. I think that the radiologists are really in a unique position to accomplish this and have made great strides in doing so.

In terms of what Dr. Sickles mentioned to you about keeping track of what you do, we also have a weekly

conference with the pathologists, with the surgeons, discussing what was done whether it be a percutaneous procedure, a surgical procedure, assessing the appropriateness of the procedure and the success of the procedure in terms of either yielding a diagnosis or as effective therapy.

So the radiologist has really become a very active member of the team, no longer the closet reader of chest X-rays. We have taken radiologists out and brought them into the light, as it were. I think we need to change the stereotype.

I won't go into the stereotype of the surgeons. I think that is something that I will leave for others, but I think it is important that we work together. The other thing that I think is important to emphasize is that, in diagnostic radiologic training, the use of imaging--imaging is at the very heart of it. You find the imaging studies just integrated without thought.

It is not an effort to use what you know in order to further your diagnostic evaluation. The facility with ultrasound, for example, is something that comes with many years of doing it. An understanding of mammographic interpretation and what goes into the making of the films is something also that I think is incremental.

It takes many years to feel comfortable with these procedures and examinations and to use them effectively in patient management. I think, at this point, it is very exciting in terms of being a radiologist who is involved with breast imaging because all of the technological and the humane aspects of medicine can be brought together in these procedures.

So I think we accept that responsibility and that is how I practice.

DR. DEMPSEY: I really applaud Dr. Winchester's broaching of the subject. I know we are very fortunate at our place and I think Dr. Winchester has a similar situation at his place where the radiologists and the surgeons work closely together as a team and there are really no problems.

I think traditionally, and I don't mean this facetiously, but many radiologists will come up and say, "Look; the reason I went into radiology is so that I wouldn't have to talk to patients." That is unfortunate. I think that is what is out there as the typical picture of a radiologist.

As Dr. Mendelson has said, that image needs to be changed. I think that if one is going to undertake working with symptomatic breast patients, and you are a radiologist, at the very least, there has to be a willingness, a real

willingness, to not only interact with, and, many times, become in deep emotional contact with, symptomatic patients but also examine them because it only is with that correlation, intelligent correlation, that you can then proceed with what you need to do.

The second integral part of what has to be the radiologist's armamentarium is a very deep working understanding of radiology-pathology correlation. What do these path results mean? You don't know that you have a concordant or discordant result unless you know what the pathology really means and you know what your imaging findings should portend in terms of pathology outcome.

So my comments are just that in order to interact with symptomatic--and I underline symptomatic--patients, because it may be that somebody is a perfectly fine screener that can screen mammograms, but once you get into the symptomatic patients or the abnormal mammogram, the radiologist has to be willing to interact with patients, examine them and have a very deep understanding of radiology-pathology correlation.

DR. MONSEES: Do you have any comments, Dr. Farrell? You don't have to, believe me.

DR. MOORE-FARRELL: I think Dr. Dempsey kind of said everything that I was thinking. I work in the setting

where it is both collaborative and I work independently. It depends on the referral pattern. Some surgeons actually refer to me to do the biopsy but they would like to follow up the patient. Many primary-care physicians refer to me and that patient becomes my patient and I manage them and refer them or follow them.

I think, as Dr. Winchester said, we are probably the exemplary radiologists. There are many exemplary radiologists out there, but not everybody. I think it is important to stress that those things need to be met by the radiologist; the follow up, the exam and the pathologic correlation.

DR. MONSEES: Any other comments from this end of the table? I would just like to stress one other thing and that is yesterday Dr. Israel was stating, and I am sure correctly so, that many of the surgeons who want to be involved with this activity have self-selected because they want to be good at this, they want to deal with this.

I think, for the most part, that the radiology community has done the same thing, that even private-practice radiologists are recognizing they need to have local experts in their groups who are the designated people who are going to all the CME courses and keeping up on this because they want to do the right thing for their patients.

I don't think it is only in the meccas that this is going on. I think that it needs to be more universal, but I think there has been a move more and more to that in that the radiologists, just like the surgeons, have self-selected.

The people who like to do this, and you have to want to do this and you have to like to do this or order to really want to be a "breast clinician" which is what I think we are talking about here, that radiologists have also self-selected the same way that surgeons have.

But, of course, it is not universal.

Do you have any other comments?

DR. WINCHESTER: I have some recommendations for revision of the document between the two colleges which, of course, then has to go back to the governing boards of the two colleges. It is not going just be done here and I am not going to get into numbers. I think that can be discussed at a different level.

But I think there needs to be some provision here for CME, for breast physical examination for radiologists performing the procedure in an independent setting. That could be qualified by saying that if the radiologist does not wish to do the breast physical examination that there should be a physician who is trained to do breast physical

examination, whether it is a gynecologist or a general surgeon or a primary-care physician.

Somebody who does breast physical examinations regularly would have a temporally appropriate breast-exam time of the mammogram; in other words, they shouldn't have a breast physical six months ago and now have a mammogram. It should be in the same time frame.

For a radiologist who would wish to acquire skills in breast physical examination, I think the American College of Surgeons would be willing to have courses, much in the same way that the radiologists have helped us in terms of imaging. That is something we can talk about at the college level. But there are mechanisms, in other words, for that training to occur. It is not impossible.

Secondly, the pathologic correlation I believe is very important as well. I don't know how to give numbers for that. You can do it through your own pathology departments but there needs to be some provision in there for exposure of the radiologist practicing independently to have some exposure to breast pathology, benign and malignant.

Thirdly, regular breast conferences or tumor board attendance is something that will keep the radiologist up to date and in a position where the radiologist wants to be,

and that is to communicate in an accurate, knowledgeable, meaningful way and not to have a conversation full of conjecture. So the database for that information has to come from source on an ongoing basis.

Again, I am not going to get into numbers about frequency of attending those conferences, or anything.

The issue of communication for a radiologist who wishes to assume, if you will, a primary breast care-giving responsibility, I think, will come easily. If all these other requirements are met, there will be patient interaction. The breast physical examination is, certainly, an entry into getting to examine the patient, yourself, and to establish a rapport with the patient.

These other things that I have mentioned will put the radiologist in the proper position for not just communicating with the patient but communicating with the patient in a knowledgeable way.

So those would be the proposals I would suggest for revision and those details can be worked on.

DR. MONSEES: I think we have to discuss some of these things. Go ahead, Dr. Hendrick:

DR. HENDRICK: I am confused by the process here. Is this of interest to the FDA? I have the feeling we have shifted from discussing issues of interest to the FDA to

discussing an agreement between the American College of Radiology and the American College of Surgeons which I, as an advisory committee member, thought was being presented as already a consensus document.

DR. WINCHESTER: May I comment on that?

DR. HENDRICK: If he is finished. Are you finished?

DR. HENDRICK: No.

DR. WINCHESTER: When he hesitated, I thought he was finished.

DR. MONSEES: That's all right.

DR. HENDRICK: I do have to breathe down here. I'll tell you, I am losing faith in this consensus process that is being brought to the advisory committee because a year ago, we had consensus that we want to go ahead with MQSA certification of stereotactic biopsy systems but we just have the little personnel issue to work out of the physician.

Now, we hear that the ACR and the American College of Surgeons don't really want FDA to be involved in the certification of stereotactic systems and the document that has finally been worked out is getting changed, piece by piece, at this committee. I just don't think that is appropriate.

If I can hear from the FDA and our chair that this is what we should be spending our time doing, then, fine. But I do have a little trouble with the micromanagement of this agreement.

DR. MONSEES: I think the reason that this is being discussed pertains to the voluntary accreditation program, not really what would be regulated by the FDA. You are right; it is a muddled matter here and it is very difficult to separate those things out.

We are getting beyond the scope of what FDA would control but we are discussing, I think, what might be a joint agreement. Do you have any comments on that, FDA?

DR. HOUN: I would say that it is of interest to FDA because we are concerned about the field of interventional mammography to understand the voluntary programs that are out there, do they meet satisfactory criteria which we ask people here, what are those criteria to insure quality practices.

We are now having some exchange on the voluntary programs, what could be improved, what could be changed. So it is of interest for us to hear what is going on in the voluntary sphere, if things are satisfactory.

In the voluntary sphere, one year ago, advice was given. Two years ago different advice was given. The field

is rapidly changing. Two years ago, there wasn't a voluntary program. As a voluntary program has evolved now to have collaboration with the surgeons, it is certainly different than it was a year ago.

So it is fine that things change and that we get different advice because of that change.

DR. MONSEES: I think it is okay outside of FDA-regulated activities if somebody wants to improve clinical practice to design a program that is in excess of anything that the FDA would have enforced or regulated. If that is going to change what happens and the FDA is no longer going to regulate because of the presence of that voluntary program, and we hear a commitment, maybe, from the ACS and the ACR, maybe things would be different in the outcome in that there would not be some regulation of the process.

I think that is what we are hearing.

DR. WINCHESTER: Maybe I can clarify for Dr. Hendrick his question. The voluntary bilateral college agreement occurred last week and was sent in the form of a letter to FDA, identical letters from both colleges. The development of the document before you for personnel requirements occurred over the last year between the two colleges.

In writing, in the Bulletin, I have stated

publicly in writing that it was my anticipation, and just talking to Dr. Bassett now who co-chaired this with me, it was our anticipation, that this bilaterally agreed-upon and voted-up by the governing organizations document would be subject to extensive committee discussion and revision based upon their input.

We expected input from you. I am sort of surprised that you are not interested in taking a critical look at this document. In fact, you did yesterday. I think that the is the process and I don't think that you quite understand it. The timetable here is important.

DR. MONSEES: I think he understands it.

DR. HENDRICK: I don't understand that it is necessarily the operation of this committee to work it out. But if that is what this committee wants to do, that's fine. I just thought it had been all worked out.

DR. MONSEES: I think it is an evolution is the way I see it. I don't know if I have an agreement from the committee members, but it clearly looks like it is an evolution, at least from the voluntary portion of it.

If it sounds like the ACS and the ACR want to go back to the table and hash out more of the details that they think need to be in that document--am I hearing that, Dr. Bassett and Dr. Winchester? Or is this its final product?

DR. BASSETT: I am not sure I can speak completely for the College, but I would think that would be the process. There are some items that were brought up yesterday that we will be considering, also. I think we are coming here for advice from the advisory committee. It is a little bit different than the usual role, but we would like that advice.

DR. MONSEES: Dr. Winchester, I know you can't, obviously, commit also for the College of Surgeons, but would you bring it back to them and ask them to revisit this as well?

DR. WINCHESTER: I think the first step is for the task force, at least the co-chairs of the task force, to reexamine the document now in light of these two days with staff to develop another one based on input from this committee and FDA, and then take it to the governing bodies again, would be the process.

DR. MONSEES: We have ACR representation in the audience. Is this okay with you if the ACR--I don't know if we have any ACS representatives in the audience. But are you listening to the gist of this conversation?

MS. ZINNINGER: I am Marie Zinninger. Certainly, we have worked cooperatively, to this point, on this and I can't believe that we will stop. So if it is the direction

from our two co-chairs that we would proceed, we will certainly take it back to our board, as Dr. Winchester will have to go back to the regions with their comments.

DR. MONSEES: Thank you.

DR. SMITH: I guess what I am looking for from a clarification standpoint is that, at least with MQSA, the advisory committee and FDA worked on standards for accrediting bodies. What we have now is a mixture of people who sit on the advisory committee also representing two organizations working out a collaborative and voluntary accreditation model which I think is a very good thing as a process.

But I guess the question I have and, perhaps, it is the same as Ed's and maybe other members on the committee, it isn't entirely clear when the critical process of evaluating and deliberating this document and this plan comes forward. Yesterday, we had a number of questions about numbers of hours of training.

We had quite a lot of discussion from both sides saying that each group isn't sufficiently trained and qualified to do one element or the other. A lot of the discussion this morning has been about that, yet this document has lots of categories of only three hours of CME.

So I am wondering when do we begin, maybe, the

critical approach of, perhaps, sending signals back to these two organizations that if we are considering a voluntary alternative to regulation at this time, how does that begin and, secondly, how do we evaluate it over time to determine that it meets all the goals that regulation might have.

I think it is actually very important to consider the alternative model to federal regulation but at what point do we begin saying the voluntary model is not working adequately.

DR. HOUN: To answer your first question, I think you, as a committee, have given advice on this document when you were asking when do you begin the critical process of giving comment on what you, as the advisory committee, feel should be improved, should be changed, to this document. You have been doing that for the last day.

There was advice on people expressing different numbers. Twelve was not enough. Twelve is okay. Eight hours. There was not a consensus, but I think the gist is that some people do feel that more should be added. Others feel okay. That was already advice and critique that was given.

We weren't asking for consensus. I don't think that the two co-chairs are asking for consensus from the committee. I think they were wanting to hear the different

opinions to get more perspective on their specific proposal. So I think that process is already happening and we are continuing now on other suggestions for looking at this document.

In terms of evaluating when our voluntary program is not effective enough, I think it is still, again, rather early in the process. We have not yet had an experience with a really voluntary accreditation program that now addresses surgical concerns, radiologic concerns.

This is just one week old. It is not yet off the ground. There is nobody yet applying for this program so it hasn't yet started. I think as we go through time, we will be continuing to ask this committee on this issue in terms of the evaluation of how things are going from your communities as well as we continue to try to gather data nationally to understand what is the public-health risk involved in this field.

What are the adverse actions? What are the problems women would have that, if we regulate, we could correct. Those questions are not easily answered because many things we can regulate may still not be fixed such as poor communication that some people have talked about from the audience.

DR. SMITH: Just in response to that, I guess I

and probably others on the committee would like to hear about the data that are being gathered on those very issues. But in terms of you are saying the process is early, we are two years into talking about interventional radiology so I am really very interested in the time table.

The other thing, from a critical approach--I agree, we have been commenting on this but I don't think any of us have really had the sense that this is a time when our comments really are going to guide the FDA in decisions about moving in one direction or another.

But when we went into the process of MQSA, we entered into a process where we were living with a lot of numbers that had become almost ceremonial; 480 mammograms a year, for example, where CME was driven as much by what is the custom of the available time for CME courses and credits, and now we are moving into another area where certain numbers of procedures have to be observed hands-on, certain numbers have to be present--without, I think, any measurable data that shows that that determines confidence.

So this, more than any other time, is the time to begin to say, "That seems reasonable. Could we have some quantitative demonstration that that is good?"

DR. HOUN: We would really encourage the professional societies, ACS, NCI, to have research in these

areas. We are not a research body but we certainly have questions of a research mode. Some of the things that are happening in the private sector among states are out there to try to collect data on this procedure on adverse events, on outcomes, performance.

It is happening out there. It is not necessarily coordinated but that is, I think, how research happens in the U.S. If ACS is able to do grants on the specific qualifications, experience, and hook it up to performance indicators, that would be great. We would encourage the colleges to encourage fellowship and research in this area, too.

There are a lot of private practices who are already publishing their experience so there is a mixture of information coming. I know states are interested in stereotactic procedures through CRCPD. So you are right. This is two years old but that may also be an indication that if there is not enough data, should we, at this point, be regulating.

DR. MONSEES: May I ask a question? One of my jobs is Chair is I did read the Act again. In the law, wasn't there money put aside for research?

DR. HOUN: The law has a section authorizing the Secretary to conduct research in surveillance for

mammography. The law was really never delegated. It certainly was not delegated to FDA. In fact, everything but that section was delegated.

DR. MONSEES: So you have got the responsibility but not the money.

DR. HOUN: We got authority to do everything but the research because they recognize that FDA is not a research organization. NCI, on its own, has taken up that area through the National Breast Cancer Surveillance consortium to do some activities in that area.

I know Dr. Sickles is a member of that consortium and they are trying to set up medical outcomes, audits, on eleven different practice communities. I am not sure it involves stereotactic performance. It does not. It is screening mammography. I think that was what the Act was screening, mammography outcomes. No money came with that, screening and diagnostic mammography research.

MR. FLETCHER: This may be well ahead of the game, but let's assume that we get back a model that we feel that the volunteer program should go into effect. Do we have any criteria for what is success and at what point we determine that a different decision needs to be made.

Is 75 percent voluntary a success? 80 percent?

DR. MONSEES: I think that is on the table that

that would have to be part of the voluntary program, that there would be a proposal for monitoring the process. Do I understand that? Would you like to discuss it, Dr. Sickles?

DR. SICKLES: I would be happy to. As far as I am concerned, and I think that this is a crucial role that the panel can take in advising the FDA, if we are going to consider voluntary programs, which I think is an interesting idea which I suspect would be welcomed by most of, if not all of, the practitioners out in the community, we have to set forth some ground rules in order for voluntary programs to succeed, as you suggested.

I can make some proposals, but I think we ought to all consider this at some point today--if you want to do it now, that's fine, but I think we have to consider what the ground rules would be.

DR. MONSEES: I think we are going to have to go back to "subcommittee." I realize that it is not part of this committee, but the group that developed--I don't think we have the time today to explore, just to say that we need to have some monitoring process.

DR. SICKLES: There are certain things basic to voluntary programs I think we should discuss in terms of the committee, that would be necessary for them to succeed.

DR. MONSEES: Such as?

DR. SICKLES: Such as what level of compliance would be acceptable. To my point of view, it has to be essentially full compliance. 80 percent means that 20 percent of the people out there don't believe that they can comply with it and, therefore, from experience with MQSA, they are the ones that are least likely to be able to comply with it.

So I would look for the panel to be recommending to FDA that something close to, if not full, compliance would be required in a voluntary program or else the FDA would have to kick in with some kind of mandatory regulation. I would look to an endpoint, a temporal endpoint, to when voluntary programs can be evaluated as to their success with compliance.

It is my sense--we can get opinions from other members of the panel but it is my sense that if there is not the implied threat, if you will, of mandatory regulation by a given time interval, that we will not achieve full compliance voluntarily.

I think we ought to talk about these issues from the panel's perspective. Of course, the FDA is going to filter that information, but I think we ought to be talking about that at some point if only briefly just to give them guidance.

DR. MONSEES: As a matter of fact, that is question 10 on the NMQAAC questions; do adequate voluntary programs currently exist or can they be created in a reasonable amount of time. Also, how will that work. So do you want to discuss that now? I would like to respond to Dr. Winchester for just a second here and say that we are moving towards describing a best practice here, not really saying what is the minimum standard.

I think we need to make sure that we differentiate that. The committee that goes, or the group that goes, to discuss this issue again, I think we need to be very careful about a best-practice model as opposed to what a minimum standard is. We, of course, want to have everybody to have the best practice but you know that is not going to happen.

We have to make sure that if we propose what we think is minimum standard but it really is best practice, it may close out some of the practices in this country and the implications of that need to be thoroughly considered.

Finally, Dr. Winchester, regarding CME for breast physical exam, I need to comment on that because I feel, as a radiologist, I don't need any breast CME right now. I feel that I could teach breast CME. I think that if we are going to talk about having radiologists do that as opposed to surgeons, why wouldn't surgeons need that as well.

I think that there are many people who are practicing radiology as breast clinicians that really are well trained in this and people who have been doing this all along. So, to stipulate that it has to be CME for a particular purpose, I would be very cautious about that kind of thing.

DR. WINCHESTER: We were when we did the original document for surgeons such as Dr. Israel. He was grandfathered. He didn't have to take all these. We would put that provision in for exemplary radiology practices now. They don't have to reinvent that wheel. They would be fully qualified at the outset so it is the issue of minimum standard versus best practice.

I think in a voluntary accreditation program or in a regulatory program that there has to be a hybridization. There has to be a blend between those two in order for it to be realistic.

DR. MONSEES: I would like to move on to the questions. Are there any lingering personnel issues, any last comments from people on the panel.

MS. HEINLEIN: Just one final comment on personnel issues regarding the technologist. Looking at what was in the ACR accreditation, I would propose that the first two bullets listed where it says ARRT-certified or state license

and then 15 hours of CME and mammography be deleted and, instead, it would be put in that the technologist would have to meet the initial training requirements for the performance of mammography under MQSA because this would say that someone could be a tech who just took a 15-hour weekend course in mammo and had never done a mammogram before and then had a few hours of training in stereo and would be qualified to do that.

So I would like to just see that changed so that they would have to meet the minimum requirements for a mammography technologist under the MQSA requirements.

DR. MONSEES: I would go along with that, too, especially when helping to position and target a lesion. You really have to be an experienced technologist to be able to do that well. I would go along with that.

Any other comments down here before we proceed to the questions?

DR. SICKLES: I just was asking a question. I don't know the answer to it but maybe we can hear from somebody in the room. Are there sizeable numbers of technologists performing stereotactic procedures now who are not qualified under MQSA? Is anybody aware of such individuals and how frequently might it happen.

MS. HEINLEIN: In my travels around the country

and visiting different breast centers and hospitals, I am currently not aware of any technologist involved that does not meet MQSA because right now anyone involved with mammography has to meet MQSA.

DR. SICKLES: No; I meant doing stereotactic procedures.

MS. HEINLEIN: I don't know. Maybe some of the application specialists, if there are any from the equipment companies might know. But I don't know.

DR. MONSEES: Theoretically, it would be possible, though, just as you say.

MS. HEINLEIN: Theoretically very possible.

DR. SICKLES: Theoretically, it is possible but if it is occurring at a 10 percent or 20 percent level, then, perhaps, we ought to address access issues if we are going to change the rules on these individuals.

DR. MONSEES: Do we have any knowledge from the audience?

MS. RONALD: Joy Ronald, Trex Medical, Bennett Division. I am an applications specialist. There are a few non-certified mammographers practicing stereotactic out there. It is not a big number. It is minimal, but it is being practiced.

MS. WILCOX-BUCHALLA: Pam Wilcox Buchalla. Just

one question that I don't know right now is in the final regs, is there a requirement for a minimum number of mammograms per year and how will that impact technologists who do primarily stereotactic if they have to be qualified under MQSA?

DR. MONSEES: I haven't seen them so I will defer to Dr. Finder.

DR. FINDER: I haven't seen the latest version either but I believe that it is in there. Hopefully, we will see the latest version today but it is in there.

DR. HOUN: There is minimum requirement for initial training and then the continued experience is an average of 100 over two years. I think the initial one was 50 supervised examinations--25 supervised examinations for the initial requirement.

MS. HEINLEIN: I have no problem with the initial requirement and the performance of 25 under supervision. However, since this is for stereotactic breast biopsy, I would like to see the continued experience requirement then change from so many mammograms per year to, instead, so many stereotactic procedures per year. I think that change would have to take place.

So I think the initial requirement could stay the same as far as learning mammogram and performing 25 under

supervision. But then the continued experience requirement would change from so many mammograms to so many stereotactic breast biopsies, as it is here.

DR. MONSEES: Any other comments on that?

MR. MOBLEY: As it is here, it was suggested yesterday to change it from 12 per year to 24 per year. I guess my thinking is that it might ought to be coordinated with the stereo procedures required to be performed by the physician because, if the technologist is working for a physician, then that person's ability to do the minimum number is going to be constrained by the minimum number that would be done by the site.

So that, in my mind, needs to be carefully coordinated.

DR. MONSEES: Let's say that that will be done in committee somewhere.

DR. SMITH: Without dealing with any specific requirement, I would just encourage the assembly of whatever data might exist, or the planning to collect data, to provide some confidence that these numbers are some adequate reassurance that proficiency has been gained, numbers of hours, numbers of exams.

It is hard for any of us who don't do these exams or have that background to really--

DR. MONSEES: How would you propose that somebody--briefly, could you suggest how something like that could be done.

DR. SMITH: Simple proficiency testing. You develop a kind of proficiency test just to determine that the person who came into this field with no experience is competent after this level of experience, or that the majority are competent after this level of experience--physicians, technologists, others.

DR. MONSEES: Dr. Sickles, you have experience with the COMISA test.

DR. SICKLES: The testing that has been developed to this point does not address the issues that you raising. That would have to be done.

DR. MONSEES: We are talking about huge observer studies, obviously, which are very difficult and very expensive.

DR. SMITH: No; this is not complicated. This is easily doable. I guess the members of the committee, I think, would be happy to work with others to develop these things. But this is not hard to pull off at all.

DR. MONSEES: Perhaps you could have a conversation with the gentlemen who are working on the voluntary accreditation program model and that could be

incorporated as one of the parts of the program.

Let's move to the NMQAAC questions. Please pull out that sheet of paper.

NMQAAC Discussion Questions

DR. MONSEES: We have discussed much of this and so what I would like to do is move--we may have to group some of these together.

Interventional mammography, what it is. Do we have any problems with what the definition is here? Can we move on? Do you all have copies of the NMQAAC questions in the audience?

The working definition. Does anybody disagree with this definition or want to amend it? If not, let's go on to No. 2. What is the present state. We discussed some of this yesterday. We don't know the number and types of procedures being performed, really, on a national level. We discussed some numbers yesterday that are in the record.

Does anybody have any updated information after doing homework overnight to any of these questions? What are the number? Who are the types of physicians? Does anybody have any knowledge about the ratio of radiologists to surgeons? I believe Dr. Dershaw said yesterday that he thought that 80 percent were performed by radiologists.

Do you have any other numbers?

DR. SICKLES: I think Dr. Dershaw's number was based on a recent publication in AJR where a survey was done. But this survey was done of radiology practices so it might be skewed.

DR. FINDER: I can provide a little bit of information on that. The database that they used to send out those forms came from SBI, Society of Breast Imaging, so it was radiologists. So they really did not attempt to go after the surgical group.

DR. MONSEES: Do we have a better idea of this then?

MS. WILCOX-BUCHALLA: In HCFA data, which is what I think Dr. Dershaw was referring to, it looks more like diagnostic radiologists are doing about 80 percent of the stereo localizations using CPT codes. That is only in HCFA data.

DR. MONSEES: Localizations? Are we talking about localizations?

MS. WILCOX-BUCHALLA: Using the 76095 code which is stereo localizations, we were unable to get data to correlate that with needle core. But, in needle core, 41 percent of those were diagnostic radiology. 43 percent were surgeons. Then, if we could get some correlation, and I would imagine FDA can get from HCFA some correlation

between the two codes, that would give us more accurate information.

DR. MONSEES: So looking at the S&I code, it was heavily weighted in radiologists. But looking at the surgical code, it was more a 50/50 proposition.

MS. WILCOX-BUCHALLA: Right. So somewhere in there.

MR. MOBLEY: Excuse me, Pam. While you have got that information, what was the other 16, 20 percent or whatever it was?

MS. WILCOX-BUCHALLA: In the needle core, for HCFA, there were 4 percent multispecialty, 2 percent interventional radiologists. So that just ups the radiology somewhat. And then 2 percent surgical oncologists. Again, it is only HCFA data and there is no correlation between the two codes that we were able to obtain at this point.

DR. BASSETT: Just to clarify, that would include core biopsies of palpable lesions and so on. So the stereo is the better representation of the actual numbers. For the stereo, what were the other numbers, Pam?

MS. WILCOX-BUCHALLA: For the S&I codes, it was 80/20.

DR. BASSETT: Oh; there was nothing besides surgeon and radiologist?

MS. WILCOX-BUCHALLA: No; again, it was multispecialty, 3 percent, interventional radiology, 4 percent, general surgical, 1 percent. I am not sure what leaps you can make from this.

DR. MONSEES: I think that it could be because people are using excisional biopsy codes. Even though the device has not been approved for excision, I believe that some people are coding this procedure as an excisional biopsy. So I think maybe that is where we are having our problems with these numbers, and other problems as well.

Do we know anything about proportion of add-on to dedicated prone units?

DR. MENDELSON: The code is not for excisional but incisional. It is 19101. It is the CPT code.

DR. MONSEES: I realize that, but people are coding it as excision biopsy, I think. We talked about proportion. We don't know. Proportion of film screen to digital. Does anybody know that? Film screen to digital; does anybody have a best guess?

DR. BASSETT: I was wondering if Richard Bird might know.

DR. MONSEES: Do any of the manufacturers care to comment on this?

MR. BIRD: Richard Bird, Trex Medical. The prone

stereotactic units are virtually 100 percent digital at this point. There are a few installations that still have film screen most of which have either converted--and I would say 100 percent of new sales are digital. Upright stereotactic biopsy has just recently been made available digital from a variety of manufacturers. I would anticipate that in the future, we will be seeing much more digital than we will film screen, but current installation base is almost all film screen at this point for upright.

DR. MONSEES: Would you have any numbers for us on a national level for how many units are out there?

MR. BIRD: I think the number that you heard yesterday was probably a slight underestimation. I think the number you heard was about 1500 prone units. I would say you are probably looking at somewhere between that number and 2000 prone units as a total.

As far as upright, I think it is very difficult to estimate, particularly how many are actively being used. Even from a sales perspective with so many companies that make upright, it is very difficult to determine. And it is even more difficult to determine what ratio of those are in current use.

DR. MONSEES: Thank you very much.

DR. HENDRICK: In reviewing stereotactic

accreditation phantom images, it looks like maybe 80 percent digital, 20 percent film screen. But that is, obviously, a selected population of stereotactic units.

DR. MONSEES: That is very helpful. Thank you.

DR. HENDRICK: I was just wondering if you have any more global data on that.

MR. PIZZUTIELLO: One other comment on the add-on units. The add-on units tend to be in lower-volume facilities where cost is a major factor. The cost of a digital add-on system is significant so I am not certain that the number of add-on units will go the same route as the prone table because people who are investing in prone tables have a busy practice. They have a lot of capital to invest. It is a good investment.

If you are only doing a few cases, then they tend to go with the add-on unit and then the large individual, the digital-image receptor, may not be compatible with that volume of practice.

DR. MONSEES: We will move on to question no. 3 which is looking at the current problem areas in interventional mammography. I think this is where we are going to start to talk about some of the other interventional procedures besides core biopsy realizing that there is no federal registration of units that are used for

this purpose.

So we all know this exists. There are units out there that have failed to meet accreditation and certification that are being used for interventional procedures such as breast needle localization, cyst aspiration, et cetera. So regulators, perk up your ears and let's talk about whether we need to regulate these units for this purpose or whether it is done on a state-by-state basis.

[Slide.]

The other thing we have up here is a list. If you can go across, you can see some of the possible problems which I have outlined here. Let's just go through this checklist and see do we have problems in these particular areas and if we have any other problems that are not on this list.

Let's start with the top line. Equipment, infection control. Let's go across, for stereo and then the mammographically guided procedures. Anybody want to talk about that? Do we have equipment or infection control problems that we are concerned about? The reason we are doing this is to decide whether or not there need to be regulations or whether or not--

DR. HENDRICK: I don't know anything about

infection control but equipment specifically--there still are some units out there that are stereotactic units, prone units without digital, that use fixed grids. I do think those are somewhat of a problem. Even some of the moving grid systems, if they are still using film screen, have large heel effects and pretty poor image quality. Certainly, the fixed-grid systems have the same problem.

The difficulty is knowing how many of them are still out there. As Richard Bird said, it is probably not a huge number, maybe 10 percent of the prone units, maybe even a little less than that. But I do think those have image-quality problems.

DR. SICKLES: In the State of California, I don't know the specific numbers but I know that regulations will permit a mammography unit to be used for interventional procedures if it does not pass the provisions for mammography as a screening or diagnostic test.

DR. MONSEES: It does allow or does not allow?

DR. SICKLES: It does allow.

DR. MONSEES: Right; that is what I was mentioning before.

DR. SICKLES: I just don't know the numbers. But if anybody in the audience knows those numbers, that would be helpful. They are certainly available from the

California--I forgot the name of the agency, but the agency that governs this. That information is available.

DR. MONSEES: Do regulators on this panel want to comment on that issue, equipment that is not certified, did not pass, is being used for interventional procedures in this nation. Is that a problem?

MR. FLETCHER: I am not sure how we would know as a regulator because when we allowed a lot of our facilities to be a part, when they were identified as being a part of MQSA, they essentially went into a different identification track. If something has fallen out and we haven't been notified, they might be in regulation never-never land. So there needs to be some way of us knowing what these facilities are.

All states, to my knowledge, have a regulatory oversight over all of this equipment. So if it is not being regulated under one umbrella, then it would fall into another. In Maryland, for example, we have a certification requirement for all of these types of devices. But we would have to know that it is no longer being regulated under mammography.

DR. MONSEES: We have so many people with their hands up. Would you like to go first? People are pointing to you.

MS. EDGERTON: Trisha Edgerton, State of California. This has been brought up with the committee before that we have had the experience, since we do certify all machines and all stereotactic needle-loc machines, that we have had facilities who can't pass CIR. And they said, "Oh, well; that's okay. We will just use it for biopsy only."

The FDA discussed, and we believe, that a second class of machines as been created, that if it can't meet the clinical image review standards, they just say, "That's all right; I'll use it for biopsy." In the State of California, they still have to pass many other tests but we don't have the clinical image review as part of our state regs. So there is nothing to preclude that.

DR. SICKLES: Do you know the number or proportion of units in California that are in this category?

MS. EDGERTON: I can think of about five off the top of my head that the people said that. It is not a huge amount. And it is more for needle locs. It is certainly not stereotactic units. It is people that then say, "Well, we use them for needle locs or other things."

MR. MOBLEY: Five out of--

MS. EDGERTON: You guys said you didn't want to discuss numbers. We have about 70 stereotactic units in the

state and, as far as straight biopsy that is not stereotactic, just needle loc, I would imagine about 30.

MR. MOBLEY: And how many total mammography facilities.

MS. EDGERTON: We have 950 facilities. 17 of those--I do know this number--17 out of the 950 just do biopsy only. We are finding that a lot of the hospitals--in fact, where it has happened is more in the hospitals because the way reimbursement occurs, the actual screening and diagnostic procedures are being done in outpatient clinics. So the hospitals open up their outpatient clinic and leave the older machine in the hospital for biopsy only for assistance in surgery and things like that.

DR. MONSEES: That is the point here; is there a specific need? Are we advising the FDA that there should be some regulation of this other equipment. I think that is the important thing on the table right now. Do you want to clarify that?

DR. HOUN: Yes. I think this issue of failed units is important. Right now, we have not been able to get data from accreditation bodies about failed units, what are those units, why they failed. So we only get information on accredited units. We have been working for the last several months on getting failed-unit data so that we can keep track

of that so that if we see failed units on inspection, there is some inventory of where they go.

DR. SMITH: This actually seems to be a classic example of where the state can provide this kind of surveillance function. My experience working with the CRCPD was always that every radiologic device was something that the state had a record of and the state wanted to know even how it was disposed of when it was taken out of service.

So it seems to me that there could be evidence of this. On this next point, call me old-fashioned, but I don't think there should be two standards for equipment. If the benefits that we are getting with mammography especially for needle localization are lesions that are really, really small, then you can't have a second class of machine to find the lesion and do the needle localization.

DR. MONSEES: I don't think you would find many of us who disagree with you.

DR. HENDRICK: I think, knowing that pattern of where equipment goes when it fails is extremely important because I would have thought that we really only needed to worry about stereotactic localization, not wire localization but just stereotactic core-sampling or needle-sampling equipment.

But this points out there is a whole category of

equipment being used mainly for wire localizations which is potentially a problem. So I think that is very useful.

MS. HEINLEIN: Again, I have no numbers but in my travels around the country, I have found that it is the 12-year-old units with manual compression only where the compression paddle doesn't hold, they say, "Oh; we will just stick it in that room and use it for needle loc." So I think there is a second level of equipment that is out there.

MR. PIZZUTIELLO: My experience also echos Rita's. In my travels, I see hospitals hanging on to the old equipment for the localizations.

To get back to one of the other questions, are there equipment problems out there. We need to remember that there is no quality-control requirement for any of these. We have been involved in some facilities where, when we began to do our own medical-physics evaluations on a voluntary basis because we recommended them as professional consultants, we have found image quality problems that were undetected by the facilities.

So we have to step out of the mammography mindset where we are thinking that all kinds of check systems are in place. These systems currently have no requirement to have any quality-control programs whatever. So I have found that

image quality problems do exist out there.

They exist out there with digital stereo units. They exist out there with film-screen stereo units. And they exist out there with localization units.

DR. MONSEES: Believe it or not, I think we may have a consensus on this issue, that the FDA needs to hear that we are concerned about this second class of units. I don't know exactly how to resolve that, but I think you have gotten that message loud and clear.

DR. BASSETT: Barbara, one of the reasons, I think, that there was an access issue or some other issues that these weren't addressed originally probably was because there was a lot more business to do. So, I wonder with the passage of this time since the Act first went into effect and regulations were being developed, wouldn't the easiest approach here be to just require that the units that are used also have to pass the same requirements as the ones that are being used for mammography?

The other details of localizations really become professional issues about performance that are going to be much more difficult to deal with. But, in terms of the equipment, would such an easy solution be too crazy?

DR. MONSEES: No; it seems quite logical to me.

DR. HENDRICK: There are a few problems with that

such as the limiting spatial resolution of digital-image receptors used on--

DR. BASSETT: No, no; sorry.

DR. MONSEES: I think he is talking about mammographic equipment that is used for the second column there, the mammographic-guided procedures.

DR. HENDRICK: Oh; you are just talking about traditional mammography.

DR. MONSEES: Aren't you, Dr. Bassett?

DR. BASSETT: Yes.

DR. HENDRICK: Oh; never mind.

MR. MOBLEY: That follows my thinking regarding this. It has been one of those things where I have looked at it and thought we have this wonderful system for assuring the detection, the appropriate detection, of disease at the front end in the screening process and then the patient is referred and falls off the cliff into the unknown as to what kind of follow up--the equipment requirements of the follow up.

I think, certainly, that the FDA moved to address the big problem with the screening but now we do need to look at that. In my simple way of looking at it, I just thought why couldn't you require that any referrals and follow up relative to these mammography findings just be

done on equipment that meets the mammography standards.

That may be a little too simple but it certainly sounds straightforward.

DR. MONSEES: Since we have fairly well finished that discussion, I would like to move on to the second part of that, and that is infection control. The other part of it that we have not talked about was the equipment--do we have any equipment problems out there with stereotactic other than the fixed grid problem.

So let's talk about infection control. This is important. This is something that was brought up the first day during the public forum. Do we have a problem with that? Do people here have knowledge of infection-control problems?

MS. HEINLEIN: The knowledge that I have of infection-control problems, again, comes from visiting many, many hospitals and breast centers. The issue of technologists not washing their hands is very real. That is an issue, an infection-control issue. I have found, though, that most of the technologists are aware of using a solution recommended by the manufacturer to clean the buckey and compression-paddle surface.

Most seem to be very attentive to doing that between each patient, but they are not very attentive to

washing their hands.

DR. BASSETT: Let me clarify. Are we talking about interventional procedures now or are we back to--

DR. MONSEES: We are talking about the whole line so you can talk about--let's talk about, first, the mammographic and then we will talk about the stereo. She is talking about regular mammography.

DR. BASSETT: Right. But we are talking about those procedures, I thought, interventional procedures.

MS. HEINLEIN: Right. But even with those procedures, they are not.

DR. BASSETT: The question was, is there an infection problem. I can tell you, having done 1,000 of each of these, probably, that I have not encountered any infection. But I would like to have the experience of the other members.

DR. MONSEES: Right. That is why I am polling this. We have vast experience amongst us, I think. If we can't come up with a single case of an infection then I think we don't probably have a big problem on a national level.

DR. BASSETT: I don't know of any from the interventional procedures from our practice.

DR. MONSEES: I would say the same with us; not a

single one.

DR. SICKLES: We have done 10,000 of them. I am not aware of one either. Generally, and I can't speak for the whole country, but generally when radiologists and radiologic technologists are involved in interventional procedures, there is greater attention to infection control at a significantly higher level than in conventional mammography because in interventional procedures, you are using sharps, et cetera.

I don't know if it is 100 percent, but there is a lot more care to infection control in this environment.

DR. MONSEES: I will open this up to standard mammography, whether that is screening or diagnostic mammography, and the issues that were addressed yesterday during the public forum as well as all interventional procedures. Does anybody have any knowledge about problems with infection.

DR. BASSETT: Could I just make a request? I really think we should deal with the interventional first so it doesn't get all muddled together because we still have two radiologists on this side who have a lot of experience. I am just making that suggestion because I am worried it is going to get muddled together.

As you know, there are some specific issues about

this that need to be addressed. I think that mixing them may be a problem.

DR. MONSEES: I will take that suggestion. On the individual side, can we hear over here?

DR. MOORE-FARRELL: I am from a smaller community hospital. Like I said, I share a machine with surgeons and we have had no problems with infection control. I have recently trained in radiology and fellowshipped in breast imaging and worked with residents, also. That has just not been a problem.

MS. HEINLEIN: I concur. As far as interventional, in none of my experience has there been a problem.

DR. MENDELSON: Neither have we. We have had no problems at all.

DR. MONSEES: Any other comments on this?

MS. EDGERTON: Trisha Edgerton, State of California. I actually conducted a study as a result of my backgrounds in nuclear medicine and radiologist. In 1990, I believe, a needle was reused in nuclear medicine that had previously been used on an AIDS patient.

The Director of the Department of Health Services asked the Radiologist Health Branch and the Licensing and Certification Branch to do a study. We picked 14 hospitals

at random, 14 places at random--I guess they were hospitals--and had a variety from teaching hospitals to district hospitals.

We looked at infection control. And we looked at medical records looking at Title 22 from the State of California. We found that, in general, and I have these numbers if anybody wants them. Unfortunately, we are going to do emergency legislation and, as we changed directors at the Department of Health Services, it languished somewhere and none of the recommendations got implemented.

But we found that, I would say, on a whole, of the 14 facilities, maybe two, after we had our entrance conference with the head of infection control, the quality assurance manager for the hospital, the director of nurses, all these people we brought in, we would say, "Okay; please bring us to the Nuclear Medicine Department and show us how you handle infection control."

They didn't know where it was. They had never been there. It was the same for radiology. We looked at why would this happen because we looked at radiology, and we looked at injections performed during fluoro exams and whatever else, and they really had never had been visited, never been overseen by the infection-control group in the hospital.

I know from the old days, being in nuclear medicine, as soon as--they used to check for infection control by doing culture insensitivities. As soon as you said you might have radioactive materials floating around, they just kind of said thank you an walked on. Typically, when JCHO, with their triumvirate of other people that come with them, they look at patient areas more like surgeon, ER. They don't come in and do--the things they look at in the radiology practice.

So I can tell you that what we found is that they maybe following universal precautions in doing some of these things, but there was not a philosophy of infection control, an overseeing body to see that they are doing what the rest of them are doing.

Something as simple as when the technologists give an injection, or in radiology when an injection is made for the purpose of the exam, it is generally not written in the chart. A nurse on the floor would never think of giving an injection without noting place, time to track nosocomial infections.

So we kind of found that they really were separated. So I think that any infection control that is going on is just from common sense and is not necessarily as comprehensive as you might think.

I have a lot of numbers but--

DR. BASSETT: I think that is good to know. However, the question was about the interventional procedures specifically. Those are usually done under sterile conditions. They are biopsy procedures. That is what we are talking about right now.

Then we were going to talk about the other issues so I would still go back and say that at least in our practice, we haven't seen any of the procedures that are listed up there. We still tell the patients that is a potential risk, but I also tell them that we have never experienced that in our practice for each procedure.

DR. MONSEES: I think what she was stating was that perhaps people's policy and procedure manuals need to be updated or whatever but I don't think what we are hearing is that there are any really adverse events that are out there, that what we are seeing is that despite the fact that people's policy and procedure manuals may not be up to snuff, we are not seeing a problem.

DR. BASSETT: Right. I am not saying that that shouldn't be addressed. We are trying to determine if there is a real serious risk.

DR. WINCHESTER: This shouldn't be confused with what we are observing in surgery when we are now doing

image-directed open biopsies following a stereotactic biopsy. I am seeing more wound complications but that is not infection-control related. That is simply inflammatory response to trauma.

DR. HENDRICK: In the literature in the large reports of, say, use of stereotactic core biopsy, they keep track of the number of cases of infection. I think there was one in 6,000 in the Parker large-scale study of core biopsy.

DR. MONSEES: Which is a remarkably small number compared to open surgeon biopsy. Since we are talking about interventional procedures, how about if we leave--we need to get through this agenda--we will leave standard mammography out for now. We are going to move on, and we will talk about stereotactic equipment, non-personnel issues, later. We will need to talk about other issues for stereotactic equipment.

Let's talk about current problems with personnel. We have talked about personnel before and what the qualifications should be, but are we having any problems that we need to note here, observed problems in the community. This is what we are talking about.

Do we have any personnel issues, problems, events that you would like to report if there were a mechanism to

report them?

DR. HENDRICK: This is anecdotal, but I do believe that there is a personnel issue on occasion, and the example that was brought up in Seattle, I think, gets to that, that there may be one or two people in the practice who really have done a lot of these cases and know what they are doing, and then there will be others who want to learn but, unfortunately, try to learn on patients.

So the concern is for the inexperienced radiologist or surgeon who wants to jump into this without the appropriate training under the supervision of a qualified physician. I have heard a number of anecdotal situations of problems being caused for the patient and the procedure not going well because of the novice trying to jump in.

DR. MONSEES: Maybe I should clarify. The reason is because what we are facing when we talk about these questions is what are the areas that may be regulated, that maybe we are going to suggest are going to be regulated. What we want to do is focus our attention on areas where there are problems. So that is why we are going through this list.

DR. DEMPSEY: Very recently, at UAV, we have been looking at the problem that I will basically describe as

continuing education for personnel like technologists. In this era of administration cutting back and cutting back on personnel, you have these things that--you have to get X number of continuing education hours.

For instance, our technologists that want to rotate into the stereotactic room need to be trained. We can talk about physicians, but let's talk about the technologists who are so integral to this. The problem is it is given lip service but then, when you try to say, "Okay; we are having three or four hours of CME training today, all the other techs have to cover," well, there are not enough techs to cover.

So we have gotten into this situation where our techs are really--and this is in general as well as in mammography--are just really lacking in CME credits, continuing on-the-job training about equipment, new equipment in our department, update on, for instance, contrast administration things in general radiology.

It has gotten to be such a crisis that we, in radiology, are going to pay a person to oversee this training and, if necessary, cut into professional funds to hire enough people to actually cover for techs to go out and get honest-to-goodness training in new equipment and new procedures.

This is a problem that is smoldering under the surface at a lot of hospitals due to tremendous cutbacks in available personnel and in personnel budgets. I am telling you that, in terms of technologists operating things that they don't know, that they have not been really fully trained in, this is going to, in our estimation at UAV--is already a significant problem that we are going to address.

If the administration won't do it, we are going to do it in our department.

DR. MONSEES: These are the kinds of operational issues where we check and balance each other. When a physician notices that there are operational issues, hopefully in your institution, you would focus attention on that.

DR. DEMPSEY: But the reason it is so significant is that it becomes a patient safety issue, particularly when you are operating core biopsy equipment. Unless these people are adequately trained and feel confident--that is the other thing. "Oh, yeah; sheet no. 4, step 3," and all that.

DR. MONSEES: That is why you oversee the operation, Dr. Dempsey. That is why the physician oversees the operation.

DR. SICKLES: There is another issue that we ought

to consider here. I don't know if you want to call it a problem or not, but it is the experience of most radiologists doing interventional mammography procedures that many--in our practice, it is 12 percent--requests for interventional procedures are inappropriate.

It is important--namely, an initial interpretation or a clinician's interpretation of a radiographic interpretation results in request for an interventional mammography procedure when, in fact, that is not the next step which should be performed.

DR. MONSEES: You have jumped down a couple of lines to procedural appropriateness of biopsy.

DR. DEMPSEY: Oh; sorry. We will skip this.

DR. MONSEES: That's okay because we are going to talk about that next if we have no other personnel problems that are identified.

MR. MOBLEY: I guess I want to elaborate on the comment Dr. Dempsey made. I don't have a specific event. It is just in looking at managed care and seeing some of the fallout. I think we are seeing it, from my perspective, at our what I would call your premier facilities. Maybe it is because I am seeing Premiere that I am using that word--but your premier facilities, those facilities that normally have had the dedicated physicist, the well-trained technologist,

the exemplary care, if you will.

We have seen those facilities begin to cut back. They can't afford that any longer. It is just an incremental kind of thing but I look at that and I say, "Okay; the exemplary facilities are cutting back and maybe now it is not exquisite, it is just almost exquisite."

But the fallout of that is, as you tumble down from the exemplary facilities, that, at the bottom end, which, obviously, we see a lot more of--I mean those are the facilities that we are into and have problems with. At the bottom end, you begin to see less and less unless it is absolutely required and somebody is checking on it to make sure that it is done, things are not going to be done.

I am just wondering how far does it get drive by managed care before, as a regulator, you have to step in and say, "You have got to do these kinds of things. They just have to be done." How far does it get driven? Do you wait until the exemplary facilities become the problem facilities and what does that mean for the problem facilities?

DR. MONSEES: It is a very tough balancing act.

MR. MOBLEY: It is and it is a concern. But I can't give you specifics. I can just tell you it is a real concern right now in my mind and I think that we are going to have to start looking at it. It may not be totally

related here but it does have potential here.

DR. MONSEES: Do we also agree--I am making a suggestion here--that the personnel that is going to do the interventional procedures under mammographic guidance, since we have not really addressed that separately, should also be MQSA-qualified individuals? Does anybody disagree with that?

I think we lost our FDA people. It will be in the record--does anybody disagree? So we agree that the personnel who do these interventional procedures should be MQSA-certified, MQSA-qualified, individuals.

MS. RONALD: Joy Ronald, again, of Trex, Bennett Division. I have great concern and I have seen it happen time and time again, especially with technologists, that there are operating out of their scope of practice, that they are compelled to do the targeting or identification of the lesions.

They are put in positions which they shouldn't be put in, so to be aware of that.

DR. MONSEES: I actually expressed that yesterday. I do believe that that is probably out there, particularly for those individuals that are not doing very many of these procedures. It may be more in surgeon practices but it may be in both types of practices, that the technologists are

being heavily relied on to do much of this procedure except for shooting the gun.

MS. THOMAS: I agree with you and I have seen it done often and time and time again. I have had technologists speak to me about that.

DR. MONSEES: Anybody else have any concern about that?

DR. BASSETT: I would be just a little bit careful about. There are different practices, there are different skills of the technologists. I know that probably the leading person in this field relies heavily on their technologist. Of course, they check everything they do. So I don't know if we can go in and micromanage how each biopsy is done.

I think the supervision has to be there. There is no question about it, and the final word has to be there, but I think there are different levels of skills of the technologists doing the procedures and different ways the practice is functioning.

DR. MONSEES: I agree. So can we leave personnel and move into procedure. The first one was appropriateness of biopsy. This is something that Dr. Sickles was just addressing. I certainly have noticed this in my own practice as well that there are patients who are recommended

for biopsy that, in fact, when you look at it again and you work them up at the time that they come in, that are cancelled. This is not just for stereotactic but it is also for breast needle loc, et cetera.

Do I hear support from the panel on that?

DR. SICKLES: I can give you some numbers on these things if you would like to have them because we have looked at this in our practice. That does not necessarily mean that our practice is representative of the country. It undoubtedly is not because we are a referral center.

On the other hand, in our practice, patients record referred for needle localization wind up with additional imaging about 12 percent of the time instead of the scheduled needle localization or the requested needle localization and about half of those wind up with no interventional procedure but simply workup of the lesion by additional imaging and no need for an interventional procedure.

In terms of stereotactic biopsy, the percentage is slightly higher. It is 18 percent in our practice in terms of requiring additional workup.

DR. MONSEES: What percent are cancelled then?

DR. SICKLES: I don't have that number. We have

done that yet. The requests for galactography come principally from clinicians. Most of those procedures are not carried out because they are inappropriate referrals because most clinicians--at least our clinicians don't seem to understand, we haven't been able to adequately educate them, as to which patients are appropriate for the procedure.

We frequently get women sent in with bilateral nipple discharge for that. We do very, very few cyst aspirations with mammographic guidance. I can't think of one in the last five years except inadvertent during a localization.

DR. MONSEES: Any other comments on the "appropriateness of biopsy" line here, across the line?

Let's move down to "failure to obtain a diagnosis." I think we need to differentiate between two things. One is that, for example, a core may be negative but, if you establish discordance, that the patient is then taken care of in some other way, and differentiate that from a patient who gets a negative diagnosis by core and then is put into the follow-up queue and, therefore, there is a resultant delay in diagnosis.

I think that it is very important to differentiate between those two things. So failures to obtain timely

diagnosis. Let's talk about that. Does anybody want to comment on this. Do we have a problem here? On a national level, do we have a problem here?

DR. DEMPSEY: Because we are discussing preoperative needle localization in this group, I am always utterly amazed at numbers that are published of "unsuccessful" needle localizations. If they are done properly with radiology surveillance and immediate communication with the operating room, why there should be almost any significant failure rate is beyond me.

Yet I see studies published where numbers are quoted on up to 20 percent. I just don't understand that. I would like other people's comments. But I have never understood that if a needle loc is carried out under good supervision with good equipment, knowing what you are going after, and then there is communication on-line with the surgeon in the operating room, why there should be a significant failure rate.

DR. SICKLES: If you are just addressing the issue of delayed treatment which is, I think, your first question-

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DR. MONSEES: I think we are talking about public-health issues here.

DR. SICKLES: Delayed-treatment issues for

stereotactic procedures, the literature would suggest that the number here of "false negative" diagnoses where one finds out that there is a cancer but it was not sampled during the stereotactic procedure is somewhere in the range of a half to 2 or 3 percent which is a very low number.

For needle localization, as Pete as alluded to, there is a range in the literature but the range doesn't make sense. The people who are quoting this generally are doing so to try to justify the one-half to 3 percent number of stereotactic procedures to make it seem similar.

But, in fact, when proper procedure is followed with wire localization, you know that the lesion hasn't been excised and the surgeon, if informed intraoperatively, has the opportunity to reexcise then. Or, if it is not done, then the opportunity exists to reexcise as soon as possible thereafter.

In our practice, there is about a 1 percent failure-to-excise rate but there is a zero percent delay-in-diagnosis rate because it is taken care of right away.

DR. MONSEES: So highlights communication and the conjoint effort of the individuals involved in taking care of the patient. Same theme.

Any other comments on this before we move on?

DR. HENDRICK: I am just wondering why we are

discussing this. Even if there is a problem here, are we going to suggest that the FDA delve into the practice of medicine and solve all this?

DR. MONSEES: No. I am not going to. But I think what we need to do for them is to highlight where there are problems. They want to know where there are public-health problems, the way I understand it. If I am wrong, correct me, because I will stop this path.

DR. FINDER: You are right.

DR. WINCHESTER: Question no. 4 is next. It says, "What problems are appropriate for regulation?"

DR. MONSEES: Right. And that is why we are doing this. This exercise is to find out where there are public-health problems so that we either solve them with voluntary process or it will be regulated.

DR. HENDRICK: Those are the two choices?

DR. MONSEES: The way I gather it is going to be.

DR. HENDRICK: How about just current practice.

DR. MONSEES: That could be. That is a third one.

DR. HENDRICK: That is a third option.

MS. HAWKINS: It was my understanding yesterday that these procedures, the interventional mammography procedures, are mostly done with younger women. I am wondering if there is not a bias with older adults with

these processes.

DR. SICKLES: Interventional procedures are done for women of all ages. Women who undergo mammography have mammographically detected findings that are not palpable even in retrospect. These are the women who require these procedures and they happen in all ages. The frequency would depend on the frequency with which mammography is done on women at these various ages.

But, in fact, the biopsy rate is pretty much independent of age so the frequency with which these occur relates to the frequency with which mammography is done on women at various ages. To the extent that it is more frequent in younger women is simply because older women are not getting recruited to mammography screening.

DR. MOORE-FARRELL: On the subject of problems--this may be anecdotal, but I will say I have seen places where the surgeons have access to the stereotactic machine and do their needle localizations themselves on the stereotactic machine. A radiologist never sees that needle placement. Some do not do specimen radiographs. Some do not do specimen radiographs of their core biopsies of microcalcifications. I don't know how you regulate that but I think that happens.

DR. MONSEES: Any other comments on that?

DR. MENDELSON: With respect to Dr. Farrell's comments, I think that specimen radiography, or specimen imaging for nonpalpable needle-localized lesions, is the standard of care and, somehow or other, that should be made known.

DR. MONSEES: How about complications. Let's talk about complications of these procedures. Do we have significant problems here that we need to know about, public-health issues? Hematomas? We have talked about infection before. Any of the panelists here know of any complications of any of these interventional procedures that are a public-health hazard?

No? Okay; so we will say we don't really know about those.

Post-procedural is where we had focussed earlier about path correlation, communication follow up. No comments? Any comments about this aside from what we talked about earlier? We think we have problems here that may fall under a voluntary accreditation; is that correct? Am I speaking a summary sentence that reflects the feelings of the panel?

DR. SICKLES: Voluntary or, if it doesn't work, mandatory.

DR. MONSEES: Do I have agreement on that?

Patient-satisfaction issues. Do we have problems with patient satisfaction?

DR. SICKLES: We have heard that we do.

DR. MONSEES: Yes; of course we do. Do we have a particular area where this is more of problem than others? Not necessarily?

DR. DEMPSEY: My hunch is--and we can't prove it, but my hunch is that the problems of patient satisfaction would be directly correlated with the amount of time spent before the procedure.

DR. MONSEES: So this is more communication, et cetera. Complaint mechanism probably ought to be considered, whatever mechanism is being used to talk about quality, whether it is going to be regulated or whether it is going to be a voluntary accreditation program, a complaint mechanism is probably important.

DR. DEMPSEY: I think the easiest way to do it is what we have at UAV. The patients are all given this communication number, that if there are any complaints at all in any direction, they have patient reps that immediately respond to any problems. But usually we would know about them anyway.

DR. MONSEES: Are there any other public-health issues, problems that need to be talked about here? Did you

have a comment first before we ask that question?

MS. HAWKINS: Just listening to the individuals who testified yesterday, and the reports that we see in the media and also in dealing with various consumer groups and, especially, older adults, oftentimes the problems we heard out there are not the problems that may come before you as practitioners.

So I really think that there should be some body to look at patient satisfaction that may be separate from basically the provision of services because when we convene focus groups, we hear very different types of problems, problems related to access, availability, problems related to just basically how services were delivered.

So I think it is a very serious problem. I think that what you may hear will be from the patients who are, more or less, satisfied. So I think it is definitely a public-health problem. I think it has a great deal to do basically with even how we will get a handle on the problem of early screening and diagnosis and so forth and treatment of breast cancer is to deal with the patients.

It may take, as I say, a third-party entity such as what is available through the Administration on Aging or other consumer groups and so forth.

DR. MONSEES: Thank you. Any other comments on

that? Okay. So we have been through these problems which I have listed up here. We can take that overhead off and let's go back to the questions.

DR. HENDRICK: I think that there is also a problem that didn't get listed up here.

DR. MONSEES: Oh, yes; any other questions? I'm sorry. I asked that question and I forgot to give you an opportunity to answer that.

DR. HENDRICK: Thank you. I don't know how extensive it is, but I think there are problems at some sites on technique factor selection, especially for digital, of sites either using too high or too low a technique to get optimum image quality.

DR. MONSEES: So this is operational issue, again. Any other problems that are out there that may be something that we want to talk about when we talk about what should be regulated? Nothing else; okay.

So what I would like to do now is look at question no. 3. We talked about the current problems in interventional mammography and that included breast needle localization and galactography. I think we can move on, then, to what problems are appropriate for regulation. That is why we have been through this exercise.

That will be questions 4, 5 and 7; what problems

are appropriate for regulation; can sufficient improvement be achieved through nonregulatory means, or through adaptation of current regs; and then, if a procedure is to be regulated, what areas might need to be addressed?

So let's tackle that.

DR. BASSETT: We already mentioned that one thing that we could consider appropriate for regulation would be that the equipment used for these procedures meet the same requirements. Perhaps, and Flo mentioned this to me, one problem would be clinical image review, if they are being used primarily for those functions but may be outside of that. I am not excluding that, but certainly that it should meet the other specifications.

DR. MONSEES: That is no. 8. So not only the equipment but the personnel.

DR. BASSETT: That was my next statement.

DR. MONSEES: Do we have anybody that disagrees with that? Any other proposals for things that need to be tackled? What else is appropriate?

DR. BASSETT: I'm sorry; we would have to realize that, in the voluntary program, there would be surgeons who wouldn't meet interpreting-physician requirements. So that is with the exception of that.

DR. MONSEES: Yes; aside from the stereotactic

program, if that were done at the voluntary program, then we would be talking about the other equipment.

DR. BASSETT: I just wanted to clarify.

DR. MONSEES: What about if there is a voluntary program, are we thinking that all of the equipment requirements should be under the voluntary program or they should be regulated? Is there a part that we would suggest be regulated and a part that would be voluntary? Let's hear some discussion on this, breaking it down.

DR. BASSETT: Could I comment once again?

DR. MONSEES: Yes.

DR. BASSETT: Just to get it out of the way. Those procedures that are being done on mammography equipment, what we call, now, conventional mammography equipment, is what I particularly thought we could get out of the way first. That would be ductographies, localization procedures, all of those, should be done on equipment that meets the specifications that are outlined for screening and diagnostic mammography.

DR. MONSEES: Yes. Okay. I think there was nobody that disagreed with that, for conventional mammography equipment. Let me ask this question. If we are talking about the alternative to regulation for stereotactic biopsy, do we want to consider that the FDA should regulate

part of that process, perhaps equipment.

Particularly, I want to hear from regulators and the physicists here.

MR. MOBLEY: I will just make this statement and it is broader than what you are asking for. I am a regulator and have been a regulator for some time. Having that experience, it seems to me--well, it is certainly my experience; let me state it this way--certainly it is my experience that until you regulate it, you really do not have the control over it if you are trying to drive 100 percent or near 100 percent--you never achieve 100 percent--but if you are trying to drive the whole community toward a standard, the only way you can do that is by a regulatory driver.

I hear the discussion here of the voluntary process. Perhaps you can make this voluntary process for the professional credentials work by saying if you don't do it voluntarily, we will regulate it. That seems to be a regulatory driver in my mind.

But if that works, then it works and that is fine. But for equipment and those kinds of things, if you don't have a standard and you don't require it be met, then it is just not done in all facilities and, in fact, maybe in many facilities.

So you have to have that regulatory driver, I believe. In this case, it seems to be--again, in my mind, it is pretty straightforward. It is a piece of equipment that is used for mammography. There are standards for equipment used for mammography. You just roll them right over there and say, "Here they are; you either meet it or you don't." It is pretty straightforward.

DR. MONSEES: Any other comments from the panel on this? Mr. Fletcher, do you have any comments?

MR. FLETCHER: Basically, I agree with what Mike has said. For equipment, in particular, I believe that there should be no option, it should be controlled through regulations. I would be very interested to see how this voluntary program works. It seem very interesting in the way it has been proposed.

DR. HENDRICK: I would agree to clear up the 25 percent that will never participate voluntarily, that having some kind of regulatory oversight of equipment, and I would add QC to that, is quite useful and, really, the only way to get that last group of people to comply.

On the other hand, when I couple that with the knowledge of how, when we say it should be regulated, inspections tend to go which is overly elaborate, overly expensive and not really getting at the real problems of the

quality, I fall back from that in the sense of wanting every piece of equipment to be inspected annually.

I think that there should be some way to meet a middle ground where the requirement is everyone has to meet these requirements in terms of equipment and quality control and to do something that gets people to meet those without requiring an eight-hour inspection annually.

One suggestion would be either to do spot inspections of maybe 5 to 10 percent of the equipment with the threat of a spot inspection any time. That would get people to comply or to have a much briefer one- or two-hour annual inspection that would see if people are really meeting these requirements and then leave them alone to do the practice of medicine.

DR. MONSEES: How about independent physicist reports. I don't consider this a conflict of interest--I consider this your advice--as sufficing for the inspections and then maybe having some random check in addition.

DR. HENDRICK: I think you need a random check in addition to that. The reason is the physicist either works for the facility or is contracted by the facility and it puts them in an extremely awkward position to be the inspector who says yes or no, they are doing everything correctly.

MR. PIZZUTIELLO: I think we have worked for a number of years to draw a very clear line of distinction between a medical physicist as a professional who is a consultant to each facility and an inspector who has a regulatory role.

On the other hand, I think that if medical physics surveys were to be sent into some central database and reviewed and spot checked on a regular basis by a regulatory function, then that would serve a better role and the physicist would still be clearly the consultant to the facility.

DR. HOUN: This is why, when we ask you about are these appropriate for regulation, regulations really lock us in. We are required by statute. If we are going to accredit and certify interventional, conventional units, we have to do on-site annual inspection. There is no discretion given to the Secretary on this.

So if it is a voluntary program and they set up a voluntary system of 10 percent audit, that is their business. But once it is FDA-certified, we are required annually to be on-site. The length of time does not have to be the current eight hours. In fact, inspections--we are looking to evolve them to, right now, 5.6 on facility reporting to us.

But we are also looking to streamline the inspection program for facilities that show excellent compliance, full compliance. So that is something we can tailor. But for the new interventional equipment that we will be seeing, I am sure we would be doing a full survey initially to get a record of how they are doing and then work with that.

DR. SICKLES: I have a question for Florence. Since the law affects what you must do if you regulate, will the law permit you to accept regulation of equipment and QC but not personnel, as Barbara was just considering?

DR. HOUN: I think that if there is not sufficient science or consensus or reason to have a regulation, we would not be promulgating in that area. We can regulate personnel, equipment, radiation, record-keeping, reporting, quality control, quality assurance. We have already promulgated those laws for screening and diagnostic.

If we want to exempt interventional because we have agreed to certain standards for equipment but not for personnel, there would be adequate basis to do that.

DR. SICKLES: So, if I understand it, you could exempt personnel but not exempt equipment.

DR. HOUN: I think that would be possible because there would be no consensus or supporting data, as Dr. Smith

was saying, on what these numbers mean. If the period of time was to allow the community to develop some better understanding of these standards, and recommend that to FDA, we would certainly hear that.

DR. HENDRICK: I think a side benefit, especially for this committee, of having equipment in the QC regulation would be to know what universe of facilities out there is doing these procedures and with what kind of equipment and how many procedures are being done on that equipment. That would be very valuable information for knowing the effect of stereotactic--for evaluating all the possible issues of comprehensiveness and some issues of quality.

DR. MONSEES: So if there were regulation of the equipment, we could, also, perhaps, recommend that and, as a result of that, we would know how many units are out there, so we would have that very important data point.

DR. HOUN: I would say that you shouldn't base regulation on collecting data. This is a big deal.

DR. MONSEES: Right; but it would be a side benefit. I think we have already heard, and it was expressed by Dr. Hendrick, that it was his concern that if equipment were under the voluntary program that there might be 20 percent or so of facilities that did not comply; isn't that right? Am I putting words in your mouth?

DR. HENDRICK: Yes; you are because I don't know what "comply" means yet.

DR. SICKLES: I would think probably a little higher.

DR. MONSEES: There would be people, there would be facilities, that would not meet the standards that we would like to have.

DR. BASSETT: I think that we are looking a little bit short-sightedly. I think that we don't have any experience with this. We don't know what the response of other societies such as the American Cancer Society, other professional groups, other reimbursement issues that might occur. It may turn out that there isn't full compliance but then we will have a program.

At that point, the program can be required. I think a lot of that work can be done ahead of time so we don't end up with some regulations that haven't been put to the test and that could turn out to be disastrous.

So I would think that we shouldn't look at this as a closed book if there is a voluntary program but, rather, just as the ACR program was voluntary, it may turn out that it has to be required. And then you would hv 100 percent compliance, which is what I am hearing. But I am hearing that we are looking at it as some kind of fait accomplis.

It is actually, I think, a development process to develop a program, see if it works, see how many people comply. If we don't get compliance, make it required. There are all kinds of alternatives that make it really not a single pathway but an opportunity to get this started in a reasonable way, with agreement of the professional societies that actually do the procedures.

I could also see how you might want to have a requirement for the equipment, itself, to be under a separate kind of jurisdiction. I suppose that is possible, too. I don't think there is any one way to look at this. I think it is more of a developmental process.

DR. MONSEES: That is what we are exploring here, whether or not we would carve out part to be regulated and part to be voluntary.

DR. BASSETT: Right; but I am hearing that it is only going to be--I understand, but I just think that we should look at it a little more broadly. We have nothing now.

DR. MONSEES: I think we will have to call on this committee again because we don't really have concordance on this.

DR. SICKLES: I would point out that the previous ACR accreditation program for mammography-covered equipment

and then, when it became mandatory, it covered everybody in the country. The current ACR stereotactic program covers equipment and it isn't necessarily so that that could not be included in the voluntary program to begin with.

Then, should compliance not proceed, that also, along with professional standards, becomes mandatory. I don't think we have to--as Larry has suggested--we have to have equipment carved out right from the start.

DR. MONSEES: I agree. The proposals are on the table. We need to discuss what we are thinking is probably the right way to start and we may or may not be able to predict how we end up eventually.

Did you have a comment, Dr. Smith?

DR. SMITH: It would seem that one of the things you could do, though, is look for proxy indicators of compliance. Let's say, for example, that a facility that is getting good scores on its inspections, on all of its screen-film units--it also has stereo units--if, under the professional societies' guidance--we are putting together this cooperative agreement for voluntary accreditation--could ask those facilities to submit to an on-site inspection that means nothing other than, "We want to just see if your QC program carries over to your non-regulated units."

That is a proxy measure of what you might expect. The other thing, in responding to Dr. Bassett's comment, is that you would really need to see some guidance, I think, from the professional organizations saying, "We are not going to trickle into compliance with the voluntary program over the next decade. We are setting a time table. This is part of a cooperative arrangement. We have spent time discussing this at the FDA advisory committees."

It is a viable alternative. But it is not viable if everybody doesn't participate. Right now, I think the spirit of MQSA is that no woman should get a mammogram in a unit that doesn't meet standards. So the idea of 80 percent compliance is really unacceptable. The idea that there are units right now being used for localization is a bit of a scandal that they don't meet these requirements.

DR. HOUN: All I can say is that when we go in to inspect, we can only inspect what we have regulated. And we can't do, "By the way, we will also check some other things," because we have no authority to do that.

That is why I would say that, as the voluntary programs develop, there are all sorts of ways that they can provide FDA with some assurance of compliance such as contracting with a third party to do some spot inspections, working with JCHO to develop this oversight, that we would

see as not necessarily a self check but actual third-party evaluation.

So things, I know, can be developed with this voluntary program.

MR. PIZZUTIELLO: The stereotactic accreditation program at the ACR has been going for about a year and a half. My understanding is that, starting in January, we are going to begin to do some random site surveys, to go out into the field to verify that the system is in place and people are really complying, and so on.

The College has been doing this in the mammography accreditation program in a big way for a long time. Until now, it is not done but, starting in January, it is going to begin under the stereotactic accreditation program.

MR. FLETCHER: One thing we may be overlooking and that is the fact that you cannot be sure, unless there is some specific language, that, if a program is not regulated by the FDA, it would not be regulated by the various states. I think if this voluntary program is to be looked at totally as a voluntary program, then some kind of guidelines are going to have to be given to the states because, otherwise, as in most other X-ray devices, the states will come in and regulate that area as they would those areas already established.

DR. HENDRICK: The follow up on that is that then we will have the same mess we had in mammography before MQSA which is 50 different sets of regulations on stereotactic and no coherence from state to state. A lot of the state regulations turn out not to be so well founded, so it is a problem.

MR. MOBLEY: I think that there certainly exists the potential to have this disparity in regulations from state to state although the states try to maintain compatibility not just with their radioactive materials program but with their X-ray program. But there are differences that exist for whatever reasons.

I think that there is a difference. I guess it seems clear to me from the discussion that we have had in the last day or so that people recognize that there is a difference between the professional criteria and the equipment criteria. It also seems to me, again, as I stated earlier, that it is pretty straightforward on the equipment criteria unless there is a reason, and we have identified, with the digital equipment for stereo procedures, that there are some specific differences that would have to be recognized.

But, for much of the equipment, it is very straightforward that it should be able to provide you the

same quality image that you would get in the screening program and it just seems very straightforward to apply those regulations to that equipment that is downstream or upstream, whichever way you want to look at it, from the screening process.

I think that you can draw a line there--at least in my mind, it is very easy to say this is straightforward and it can be done. This is just the way regulatory programs evolve. You address the big major issues first and then you look at, okay, are there additional areas that we can effectively deal with and where do we draw that line.

In this case, it seems straightforward on the equipment. The professional qualifications, and those issues, are certainly nebulous in my mind and I would say, from the discussions I have heard, are quite nebulous in the collective brainpower that is presented here because there are, obviously, very different perspectives regarding that.

It is not, in my mind, ripe for regulation at this point in time. It is ripe, I think, for a driven voluntary process. So that is two different things. One is the machine process, straightforward, clear, regulated. The standards are in place. Go for it. The professional qualification; it is not straightforward. It can be driven with a voluntary process, with a regulatory driver in place.

I think that is the way we should go for that.

DR. MONSEES: Can I just clarify something because I am not sure I understood this. Maybe I just missed the comment. Are you differentiating between stereotactic equipment and conventional mammography? I think we agreed that conventional mammography equipment ought to be regulated to the same standard as it is for use in screening and diagnostic purposes.

Are you saying that you feel that the equipment for stereotactic use should be regulated at this point and separated from the professional qualifications which could be voluntary? Or are you saying that the whole stereo program could fall under voluntary.

I would like to hear your opinion about that.

MR. MOBLEY: Yes; I am saying it should be and, in fact, it will be, as noted by Roland and Ed, by the states. My concern, I think, is probably along the same lines as Ed's is that when you get into these kinds of situations, depending on the level of understanding you have of the equipment, the qualifications of your inspectors, you can get some very strangely driven criteria.

DR. MONSEES: So it is a yes. You want to regulate it.

MR. MOBLEY: I want to regulate it but I believe

that we need some clear-cut baseline standards that will give the states, and/or if is a federally driven thing, give the states a straightforward, "Here is the way that you would regulate these things." Otherwise, you have got a situation where you may have, "This is not a federally regulated device."

The state, then, says, "Okay; how am I going to address this thing? Do I apply conventional fluoro standards? Do I apply radiographic standards? Do I apply pixelscope standards to this? And how do I do this?"

Well, depending on the way that the inspector might look at it when he is there when you are in one of these never-never-land situations, it could be really tough.

DR. MONSEES: I get the drift. I assume that Mr. Fletcher agrees with you.

MR. FLETCHER: Yes; I do.

DR. MONSEES: Dr. Hendrick, do you agree?

DR. HENDRICK: Yes; I agree. I would also like to say that I still think, if you present this to a woman, the equipment that you have a one, or a few, per-thousand chance of having cancer detected on is regulated but the equipment that you have, like, a few in ten, or a one in ten, two in ten, chance of having cancer tissue-sample done is not regulated, I think they would have a problem with that.

But I also think that there are problems if you say equipment should meet standards, the QC should meet standards, that should at least include the qualifications of the people providing that QC service, the physicist and the technologist.

DR. MONSEES: So you are one-upping it and you are saying not only the equipment but you are suggesting that the qualifications of the people that perform QC also, perhaps, be regulated.

DR. HENDRICK: I up it to the technologist performing the procedure, too. But I don't think that is an issue. I don't think we are debating, really, the qualifications of the technologist or the physicist.

DR. MONSEES: But we are whether or not it should be regulated or part of the voluntary accreditation program, perhaps. We are.

DR. SICKLES: I have a question to the people who are expressing interest in immediate regulation of the carved-out portions. Would you feel differently about the acceptability of a voluntary program if it had a narrowly defined definition of what acceptable compliance was and a time line where it had to be achieved?

For example, if we had a defined near-100-percent compliance within, say, a year and a half, would that be

acceptable to not having to carve it out or is it your feeling that this simply has to be done immediately?

DR. HENDRICK: Are you talking about with regard to equipment and QC standards?

DR. SICKLES: I am talking about equipment, QC, technologists, all of what you were just saying.

DR. HENDRICK: But, see, I don't think if you don't have some kind of way of assessing how many facilities there are out there that you will ever know that you have 80 or 90 or 100 percent compliance.

DR. SICKLES: Agreed. I think it will be the responsibility--in any voluntary system, it would be the responsibility of whoever is trying to prove that that is adequate that they have full compliance. Somebody is going to have to figure out that they have got full compliance. If you can't demonstrate that from the start, if you don't have a way to monitor that, then a voluntary program makes no sense.

DR. HENDRICK: I agree.

DR. SICKLES: But assuming that a voluntary program could be devised that could monitor the level of compliance and that you had a time line defined, absolute, "meet it or we regulate," would you still insist on regulation up front?

DR. HENDRICK: No; not at all. That would be the best of all possible worlds.

DR. SICKLES: I just wanted to clarify it because I thought I was hearing from my side of the room, from the right-hand side of the table, that we just had to regulate immediately. I am not sure that is the case.

MR. MOBLEY: Regulate what? The equipment or the professional standards?

DR. SICKLES: Would you accept any voluntary program defined any way that you would--let me put it this way; would you rule out any voluntary program no matter how strict the rules might be for equipment, QC, personnel up to technologists? Would you rule out anything voluntary because you feel it just has to be regulated right up front, there is no possible way that it could work any other way?

MR. MOBLEY: No; I wouldn't rule it out. I would feel like that would be terribly arbitrary on my part to say, "No; we are not going to listen. We are not going to hear of that." I am just saying that there are other situations out there within the states where the states will fill in the void because of their perspective regarding it if there is not some national guidance.

Generally, a voluntary program is not the level of guidance that would be necessary so you could have states

step in to fill in that gap in certain instances. I don't see, in this case, that--I guess I don't think it is a big issue whether it is voluntary or regulatory.

The real question is how do you assess the voluntary program, in particular with Dr. Houn saying they can't do inspections of this unless they have a regulation in place. I don't know. I couldn't rule it out but here is what my perspective would be.

It takes time to develop regulations and things. If, in the time that it took to develop the regulations--I mean, we are saying do this immediately--will immediately, in a regulatory arena, particularly at the federal level regulatory arena which is a year, two years, maybe a little bit longer--

DR. SICKLES: What I am trying to get at is should the FDA begin the process of regulation, in your opinion, now or should they indicate to the community at large that they are very interested in this and that they are aware that their voluntary program is being set up right now which they will monitor to the point where, at a given point in time, if they don't meet certain standards the FDA has in mind, that it will be regulated.

Those are the only ways that voluntary programs will work.

MR. MOBLEY: I guess my perspective on that is that I think the FDA should begin immediately to devise this program, to look into it as to how it would be set up and implemented for the equipment and go forward with it. If, during the interim, a voluntary process was developed that could demonstrate that all the standards could be appropriately met by the facilities, then you could take a look at it at that point in time and say, "Maybe we don't need those standards."

But I think you should move forward. There has been too much discussion about the potential need, should we do this, et cetera. I think it is really clear from our discussions here that yes, we just need to clearly say, "This has to be done. We are going to proceed to do it."

If, in the meantime, a voluntary program does address the issue, then you could take a second look, just prior to promulgation of the standards.

MR. FLETCHER: I guess one of the things, as a regulator, you have to think about is what is the impact of setting a precedent, particularly when you have established criteria, and where is the ripple effect. Over the last couple of weeks, Mike and I have heard arguments in other arenas, medical arenas, whereby the need for the type of regulations that currently exist may not exist anymore.

So the possibility of coming up, even after a regulatory program is established and to demonstrate that that level of regulation is no longer necessary and that a voluntary program will work, that is possible because it is ongoing right now in another arena.

However, from the other side of the coin, as a regulator looking at the equipment, if I allow, or just don't regulate, a type of equipment that is in the same arena with other broad types of equipment that I do regulate, questions are going to come from that community, "Why are you regulating this and not this?" even though it is not stereotactic, fluoroscopy, et cetera.

"Why did you give an exception here? What is the proof needed to put us in some kind of a voluntary program?" So, as I said, as a regulator, I have to be concerned about setting a precedent and what the ripple effect of that precedent is.

DR. MONSEES: Dr. Smith, last comment, and then we are going to go to break.

DR. SMITH: I am going to make this a long comment. One question I guess I would have is would the states--this is something that I don't think that the states can answer right today--but in keeping with Ed Hendrick's earlier comment, if we were to pursue the idea of a

voluntary program, number one, I think that the professional societies would have to say, if this were developed in parallel, which I think Mike's idea is a very good idea, we want to have this voluntary program in face a lot faster than the FDA could put a regulatory program in place.

In fact, by definition, you will need to because otherwise the FDA program would have to kick in. That would be the consumer groups' recommendation and endorsement. In other words, the cancer society would have to opportunity to simply say, "We are going to weigh in on one side or the other based upon the evidence that we see that the protections are in place." And they would have to be nearly universal.

But the question I would have for the states, also, is, would, under the CRCPD and the collectivity of the states, they be willing to collaborate in this process and not embark upon, once again, a patchwork of different kinds of regulations, in a sense, jump the gun on this, to give the professional societies that opportunity to demonstrate that a voluntary program can work.

The last question is that you can't have any assessment, or any evaluation, unless there is some cooperation at the state level for the kind of surveillance to indicate the universe of machines that is in the

voluntary program and the universe of machines that is out there.

That was always kind of the uncertainty that we had. Right now, it doesn't appear all of these units that can't pass MQSA and they say, "Fine; we will just roll it into the next room and use it for something else," that is clearly in violation of the spirit of MQSA.

The states do, I think, have the authority to say, "The FDA may allow you to do that, but we won't." Have any states taken that step? That should keep us busy. Do you want to do that after the break?

DR. MONSEES: Why don't we break now. What we will do is we will answer that when we get back and then we will proceed with the rest of the NMQAAC questions. We will reconvene at 10:45. Before you leave, Dr. Finder would like to make a statement.

DR. FINDER: I have two issues I want to bring up. One is a list that I am going to pass around for people to put their names and tell us what type of computer system they have at home so we can send them transcripts on disc.

The other thing I would like to do is make a little announcement. Many people may know that several of the members currently serving on this committee, this will be their last meeting. I just wanted to extend my

appreciation, the Division of Mammography's appreciation, and the Food and Drug Administration's appreciation for all the work that they have done.

The people that, unfortunately, will not be coming back for the next meeting are Dr. Lawrence Bassett, Dr. Tamsen Bassford, Ms. Marydale Debor, Ms. Rita Heinlein, Dr. Ed Hendrick, Ms. Maria Romero, and Dr. Robert Smith. I hope I haven't missed anybody.

But I do want to thank everybody for all the hard work and the effort that they have put into the various committee meetings over the last three years.

[Applause.]

[Break.]

DR. MONSEES: We are going to begin the discussion again this morning. Because Dr. Smith posed some important questions, I am going to ask him, in one or two sentences, to just briefly to recap those questions before the panel, the deeply important issues.

DR. SMITH: Before the break, the questions that I posed are in order to determine levels of compliance, I would think that the states would need to cooperate with the voluntary program to identify the universe of sites, facilities and equipment that would need to be covered under the voluntary program.

So that would be one thing, the whole issue of what is out there and what is covered and what kind of compliance do we have is only possible, I think, with some cooperation from the states.

Secondly, if we are going to avoid another patchwork of different regulations and programs and standards for this particular technology, if FDA is willing to experiment with the idea of a voluntary program that meets all the goals of a regulatory program, will the states cooperate during this experiment by holding off on establishing their own regulations.

I think the third issue is just really related to the idea that there are units, if they did not pass an image-quality test, were pulled out of coverage under MQSA and began to be used for other procedures, are there any states that have stepped in and said, in effect, if MQSA would allow you to do this, the state won't?

Now, the last question probably only can be answered on a state-by-state basis, and we have a couple of states here. But it is an example of where local control might have had an advantage where MQSA, right now, couldn't.

The two critical issues, though, are the first two, levels of cooperation as well as holding off during the experiment period.

DR. MONSEES: We will start with Mr. Fletcher.

MR. FLETCHER: The best organization to facilitate state cooperation is, of course, the Conference or Radiation Control Program Directors. There are established, and Mike can probably talk to this even better, already organized mammography committees that work on various aspects. That is the best level of cooperation because they can get all of the states communicating on the issue, get the issue out to everyone simultaneously, because understanding the issue is going to be as important as what resolution comes from it

The thing that I think you, perhaps, need to be aware of is that states will probably not develop any new regulations to do this. What will happen is if this is a category of devices that is no longer regulated under an MQSA umbrella, it will fall into a category that already exists in the states. States already regulate all other forms of devices.

So I don't think initially there will be a mad rush to establish a bunch of new regulations. The CRCPD does have a council that deals with suggested state regulations. That is how we get our uniformity. The unfortunate part is it does take some time for the development of these regulations as it does with any large organization where you have got to get the cooperation of 50

states or at least the coordination of 50 states to come out with a solution.

But the mechanism to do what you call for is already there. It is just a matter of making sure that it goes to work.

DR. HENDRICK: My concern is that it is going to take some care to develop reasonable equipment specifications where digital is concerned--not specifications, but performance requirements where digital is concerned.

I think that would even take this body probably a year, given the way things proceed, to develop those reasonable equipment and QC specifications or requirements if you were to have an MQSA-propagated equipment certification for stereotactic. It sounds simple, but to work out all the details--you have film-screen, upright add-ons for stereotactic. You have digital upright add-ons for stereotactic. You have prone film-screen and digital.

It is not trivial to write things that cover all those. I would much rather see this body do it than either individual states or the CRCPD try to do it from scratch because I think that this body does capture a lot of the expertise that is needed to do that.

Further, I don't think we live in the best of all

possible worlds in the sense that I don't think people will just voluntarily comply with this. Experience has indicated that 80 percent will, 20 percent probably won't, and that if you went up along this path of saying, "Let's let the voluntary program have a chance to demonstrate that it works," you would be three or four years out waiting to collect the data to see if it works and that would be three or four years of wasted time in developing sort of unified national requirements even for the equipment.

So I don't think that there is anything lost in pursuing parallel paths of developing at least the equipment and QC nationally under this committee while you let the voluntary program play out.

DR. MONSEES: So a recommendation for parallel paths. Mr. Mobley, did you have a comment on this?

MR. MOBLEY: Yes; I just echo Ed's comments and give a quick statement. I think, generally, that states, particularly if it were coordinated via FDA through the conference, that the states would give the process a chance. But we have to recognize, in every case, when we are dealing with 50 states, that there are local issues that may cause a state to have to take action based on whatever that local issue is.

Whereas the states, collectively, might say, "Yes;

we can give this process time," we do want to see movement. We do have to recognize that there may be individual states that are caused to have to take action at some point in time and that is just the way it is.

I believe Bob asked a question about the universe of machines. I have been really struggling with that, the universe of machines, the universe of procedures out there, devices, whatever we want to call them. I guess if they are machines, they are devices. It seems to me that we ought to be able to capture that information fairly readily by polling the states as to what, from their facilities that they inspect, where are the referrals going to.

If we have to collect that information over time, then we can collect it within a year's time frame or, if it were needed in the near term, we could poll those facilities directly with a letter, questionnaire, or whatever. That information just seems to me could be available to us in the near term, near term being six months.

MR. PIZZUTIELLO: I think you are right, Mike, that we can probably get that information from the states because of their registration program for X-ray equipment. However, I don't believe at this time, at least not in my state, that there is any requirement to register and add-on unit. That is something that is going to be a much more

difficult nut to crack.

As we have heard before, there are lots of add-on units sitting in corners holding doors open. So that is another area that is difficult.

I think, to get back to Ed Hendrick's question, there hasn't been a lot of talk yet about what might happen if reimbursement were connected strongly to an accreditation program or combination of programs. Ultimately, in the market, what we have seen is that professionals need to get paid in order to continue to do this work and, if there were such a strong connection with HCFA, then that might ensure a very rapid rise toward near 100 percent compliance.

If that were the case, then some of the concerns about the 80 percent versus 20 percent might go away. That is something which, I understand, has been successfully done in another area--I think it is intravascular ultrasound--and it might be possible for the voluntary bodies to negotiate something with HCFA.

You would probably have a sense, in a relatively short time frame, if that is even possible or not. So I would wonder if that is an avenue that might bring us more rapidly to near 100 percent compliance.

DR. SMITH: I think that is possible. CDC, prior to MQSA, make it a requirement that any reimbursement under

Title 15 would only be available of the facility were accredited by the ACR program. So CDC would also be a very useful avenue for requiring voluntary accreditation for any women getting breast biopsies under its program as well, provided that they move into the area of reimbursement for biopsy which is something, I think, they are considering.

DR. MONSEES: Do you have a comment that pertains to this?

MS. EDGERTON: I had a response to Bob's original question. You were asking state's experience that regulate stereotactic units and biopsy units. We have regulated them and inspected them since July 15, 1993. We require the same things that we do for general mammography procedures.

We did put forth our own documents that have to pertain to that. It is not under regular radiology equipment, as Roland was referring to. So, on the state level, we do not have CIR, but they do have to meet image quality. Now, the new stereotactic with the digital--we didn't define a digital dose back then because it didn't exist. So there is no dose limit on digital equipment.

They do have to do the same QC, QA. They do have to have an annual physicist come in and review the equipment of which we have had some problems because many of the physicist reports coming to us are inadequate in that some

of them don't realize you can move the needle out of the way and actually do a lot of tests. I think you alluded to that earlier.

It is getting better. We have actually had to train some physicists to do this. Then we do the annual inspection and we look at all that. We have had many facilities that were confused with the federal regs saying that because it is not covered under federal, they aren't going to do anything with it; "I don't have to do my QC. I don't have to do my monthly phantom," and all these other things.

And we have said, "Yes; you do. This is state, now. You are under state regulations." So I have had to write letters. I have got a stock letter that I provide to physicists who are out there telling their clients, "Yes; you do have to do this."

So they just carry these copies around. When the facilities say, "No; I don't have to do anything with these units," they say, "Yes; you will be inspected and you do have to have the annual physicist report and all that."

I don't know if you had any other specific questions with respect to that.

DR. SMITH: No. But, in response, it sort of reinforces Ed's point about the strict importance of a

parallel program, as well as with the voluntary program, with time lines that are in the very near future because, even now, MQSA, and all we have been through, hasn't made true believers out of everybody.

We have had quite a lot of anecdotes this morning of facilities who are saying, "It is just my good fortune this doesn't fall under MQSA and I don't have to do any of that stuff."

MS. EDGERTON: Right. Since we do check the image quality and we do check the QC/QA, they are not failing. They are not being pulled out of service as a result of that. I think the ones that failed on clinical-image review, a lot of it was compression related. I think you can demonstrate, still, that the compression paddle, we do check it, does it hold for the required amount of time.

But we found so many of those that failed appeared to be inadequate compression with resulting motion, loss of image sharpness, loss of exposure, even exposure levels and things like that. Since CIR is not part of what we do at the state level, we are unable, necessarily, to pull these units out of service even though I think they do finally disappear because they are the older units.

I don't know if it was Bob mentioned that it is the older units that are left in the hospitals. They move

the nice new ones to the outpatient facilities because of the CIR and then they retain their old 500Ts. Luckily, all the Sureviews are gone. Finally the attrition rate--the old units are going away.

MR. FLETCHER: I just have one question because someone--I think it was Dr. Pizzutiello--asked a question about registration of add-on facilities. The only way we would be able to track those is if there was a certificate of installation even with the add-ons. If there is a certificate of installation or an installation form, we can track them because they become part of our registration process.

At least, that is how it would work in Maryland. I think that is how it works in other states.

MR. MOBLEY: It would not work that easily in Tennessee, but I guess I look at it taking another tack, and that is going to those 200 facilities, roughly 200 facilities, in Tennessee that do screening mammography, they make referrals somewhere. I would presume that most of them make referrals to one or two facilities.

I would propose going to those 200 facilities and saying, "Who do you do your referrals to for this type of procedure?" or "Who do you do your referral to, period?" and then look to see what it is they have registered. That is

easier than polling or going through 12,000--I've got roughly 5,000 facilities with 12,000 X-ray devices.

So I would really go to those 200 facilities. I can even make personal visits to the 200 facilities if I have to before I would ever track through all these 12,000 devices and figure out who was what.

DR. SICKLES: Just one comment related to what we heard earlier. I think it is going to be extremely difficult to get the denominator on add-on units first of all because they are simply attachments to an existing mammography unit, and, secondly, to get an indication of whether they are actually being used because many people have purchased these in the past and then, for some reason or another, they have gotten a table unit and they don't use the add-on unit anymore.

DR. MONSEES: That is an important point.

DR. SICKLES: That is a very difficult thing to get a handle on.

DR. MENDELSON: I think there are two problems that we have to address and they are separate. One is, and we keep going back to it, we really don't have full information about the location and number of prone tables that are in current use and those that are in the process of being installed and will be installed in the next year or

two.

There are two major manufacturers of these tables and we really need their cooperation for better patient care overall. We are very concerned. The MQSA regulations have done a lot for mammographic quality and for patient care. As an extension of that, we probably need this information. Whether or not we get it through registries on a state-by-state basis or whether the information and the locations of these tables is something that will be given to us for use in formulating either voluntary accreditation processes or one that is supported by legislation is something very important.

So I think we need that information and we must have it. Before we do anything else, I think that is crucial in professional use.

The medical use of these tables is changing. We see that when we started with the voluntary accreditation program of the ACR that we were dealing, really, with one specialty and that was diagnostic radiology. Currently, as times change and uses change and the evolution of medical practice is something that we are all involved in, we see more than one specialty now involved in the stereotactic core biopsies.

Whatever we come up with as an accreditation

program has to reflect that. That is what we have been talking about and what the professional eligibility requirements are, criteria-based credentialing, a variety of things there; education, both initial and CME follow up.

All of these things hinge on things in medical practice. So, first, we need to know where the prone tables are, who is using them, where the ones that are being manufactured now are going, where they are slated to go, what the plans are in that regard.

Second, as far as the voluntary accreditation program is concerned, we have one. The American College of Radiology has worked on one. In looking through it, it should be acceptable, possibly with some modifications, to everyone who is doing these procedures. There is no reason why surgeons who are not interpreting physicians as a category for interpreting physicians--the surgeons who spoke yesterday disclaimed any part in mammographic interpretation. That is not what they do.

They may be performing physicians in terms of these procedures, but they are not interpreting physicians. But looking through the ACR stereotactic breast-biopsy accreditation program, it certainly is usable and mature enough to be used as a start in getting a program like this going.

I think it is crucial that we do that and this, I think, is a very good document.

DR. MONSEES: Any other comments on that?

MS. EDGERTON: I know Pam is probably going to smack me here, but there is a potential for you guys finding out this information. Those of us who have looked at the new FDA database that they are requiring us to use as accrediting bodies have looked ahead to categorizing these units.

There are certain fields in there that are not to be used now but might be; that is specifically, they have for each machine--it is unit-based. Machines can be categorized as stereotactic and add-on units. In talking with them, how we are going to implement this database, we are hoping--because, otherwise, we have to keep a separate database on our biopsy units.

We are hoping that we can at least just put this information in one database, put in our units that are stereotactic and add-on--they won't go through clinical-image review but the data will be there. We all do annual update forms and there might be a way that, through the accrediting bodies on an annual update form, that this information could be added and uploaded to the FDA.

So there is a potential there for that.

DR. MONSEES: You are talking about for the add-on units.

MS. EDGERTON: It separates add-on and stereotactic units. So there is a potential for a national database on that.

DR. MONSEES: Any other comments on this? Are there any other issues that maybe we want to talk about that we are suggestion regulation may be needed or contemplated? We have talked about equipment. We have talked about mammographic equipment and we have, I think, pretty much universally decided that we have an opinion that that equipment should fall under MQSA.

Are there any other pressing things? We went through this list of potential problems that exist for public-health safety issues. I need to know if there are any other suggestions on the table before we move on to the next NMQAAC question.

Before I turn it over to comments, let me just revisit and remind you that infection control has been a question. Ms. Edgerton made some comments before about some research that she had done.

If anybody would like to comment about the adequacy of infection-control programs--it is different, obviously, in hospital situations than it would be in an

office situation and would we like to consider whether, in a voluntary situation or in a regulatory situation, that some wordage pertaining to infection control might be included in there and is there any other issue that we would like to have the FDA hear us suggest that they need to look into?

DR. SICKLES: Only in relation to the questions that were posed previously where we are going to get to item 9 which will address some of the questions that were raised before, just to put that on the record.

DR. MONSEES: Okay. Anything else here that is of concern?

DR. HENDRICK: I am not sure where we left the issue of the non-physician personnel with regard to stereotactic.

DR. MONSEES: Do you mean with regards to whether or not we were recommending that this be regulated as opposed to--I think what we have done is--we are not trying to achieve consensus. We can poll and ask other opinions, if you would like, and we can revisit this now.

I think what the FDA wants to hear is our voice about this but not necessarily that everybody agree on it.

DR. HENDRICK: No. But I just thought it got brought up and it never really got--

DR. MONSEES: Okay; then let's relook at that now.

Dr. Hendrick was proposing that not only should we consider the regulation of the actual equipment but that there be some personnel issues that might be included in that regulation. I would like to hear some other opinions about this.

MS. HEINLEIN: I have a problem with saying that we will go with regulation of personnel dealing with interventional mammography up to the level of the technologist. There is the medical physicist that we are willing to regulate. And then there is the technologist that we are willing to regulate. But we are not going to touch the "p" word--the physician.

Who is ultimately responsible? I am saying if you are going to talk about regulating personnel, then there are three. There are not two; there are three. So I would suggest that if we are going to discuss personnel, I don't think we should separate them out.

I think we should say all personnel. I think the discussion before of developing a parallel pathway and going with a voluntary program and, at the same time, developing regulation is a very viable way to take it. But I don't think we should separate and say, "Well, we will just take these two people, the medical physicist and the technologist, and we will develop an alternate regulatory

pathway for them but we won't do that for the other one."

DR. MONSEES: Would you care to respond to that? I know you would.

DR. HENDRICK: Yes. Is there a reason? What is the reason about not wanting to have requirements for technologists, you of all people.

MS. HEINLEIN: No; I am saying I want requirements. I am saying I want requirements for technologists and medical physicists and physicians.

DR. HENDRICK: But I don't follow your logic. If we know how to write requirements for technologists--the technologists are doing the QC; isn't that important? The technologists are there managing their part of the procedure which has a lot to do with patient interactions; isn't that important?

MS. HEINLEIN: Correct.

DR. HENDRICK: Do you want this to be done by secretaries?

MS. HEINLEIN: Ed, duh. What I am saying is I agree with everything you are saying. But I am saying you are only focussing on two aspects of personnel. You have left out the third. You said up to the technologist.

DR. HENDRICK: Right.

MS. HEINLEIN: I am saying why exclude the third

person?

DR. HENDRICK: Because we don't have consensus about the personnel qualification requirements for physicians.

MS. HEINLEIN: This has nothing to do with consensus. We are giving an opinion to the FDA as to whether or not, if we are going to offer regulation, should it cover all personnel or only two-thirds of the personnel involved.

DR. HENDRICK: Right. In the world we live in.

MS. HEINLEIN: Right. And I am saying if we can have an impact on that world, I am putting my opinion on the table to say it should cover all three personnel. Do you agree that it should cover all three?

DR. HENDRICK: No, because, by doing that, what you are going to end up achieving is no personnel qualification requirements whatsoever which I think is worse than having two out of the three.

MS. HEINLEIN: I say I want all three regulated. If the physician is the one that is responsible for the targeting, if the physician is the one that is going to be responsible for the tissue that is being taken out, I want that person--if there is regulation, then it should be for all people involved.

DR. MONSEES: Can I just clarify here something that you just said. "If there is regulation." Are you suggesting that there be personnel regulation at all or are you saying that it should go the voluntary way but that all three should be treated equally--in other words, the technologist and the physician--that you would prefer to see them under voluntary or that you are stating your opinion now that you think that everything should be regulated.

Would you clarify that?

MS. HEINLEIN: Yes. I said I am all for trying the voluntary pathway and, at the same time, starting to work on development of regulations so that you have a year and a half or two years to see how the voluntary program--if it is effective. Then, if not, you already have these other things in place that you can move into.

DR. MONSEES: Okay. Got you.

MR. FLETCHER: From a regulatory perspective, I agree.

DR. MONSEES: I'm sorry; I am not sure what you are agreeing with?

MR. FLETCHER: I am agreeing that all personnel should be looked at equally.

DR. MONSEES: Equally, but are you stating a preference for voluntary versus regulatory?

MR. FLETCHER: I also agree that we should give the voluntary a chance but don't just sit back and wait. At the same time, while the voluntary system is being allowed to work, we should keep in mind that a regulatory system needs to be ready to go into effect.

As I said before, voluntary compliance seems to be two opposing words but that is what I have heard used here. You either comply voluntarily or we will regulate. I don't have a problem with that process but I think to treat the personnel who are part of the system differently because of their credentials is improper.

DR. MONSEES: You think voluntary compliance is an oxymoron.

MR. MOBLEY: I, too, agree. Specifically what I agree with is I believe that we can give the voluntary process the opportunity to see where it will go but, at the same time, we need to develop the regulations. But I would note that there are times, from a regulatory perspective, when an issue is ripe for regulation.

From my perspective, the information that has been presented here tells me that I believe that the technologist and the medical physicist issues are fairly clear cut. I think they are ripe for regulation fairly straightforward.

The physician issues, in my mind, are still

somewhat up in the air. That doesn't mean that you can't move to deal with those and, during the interim, perhaps they will become ripe and be addressable.

But, perhaps, they won't. In developing regulations, it is always very important to assure yourself that what you are regulating is effective, does what you want it to do, does not unnecessarily constrain the practice that you are attempting to regulate.

You are providing the protection for the public but, at the same time, you are allowing the benefit of whatever process it is that you are attempting to regulate. From my perspective, I don't think--the physician qualifications issues are not ripe in my mind.

The other issues are fairly straightforward and I am ready to regulate them today. But we have got to go through the process.

DR. SICKLES: I just wanted to make the point--Mike started this and I just want to emphasize it--that FDA does not really need to be told--I'm sure that they know--that it is going to be harder to write regulations for physicians when it is a moving target that they are trying to regulate.

Those of you who have been on the committee for years have seen an evolution in what the different physician

groups have been asking for. What they are asking for this year is different than what they asked for last year.

What they ask for next year might be different than what they are asking for this year. Until there is some final consensus from the groups, it is going to be hard to write regulations. So I expect that, although they will be writing a parallel track of regulations for physicians, it is going to be very vague, at least from the FDA point of view, until they see more consensus because it is going to be very hard to achieve one.

If, in practice, it takes them a year or two to write the regulations and get them promulgated, by then we would hope that the voluntary process has congealed to the point where there is consensus.

If it hasn't, it doesn't have any future. It is going to be regulated. So I think you are really talking at cross purposes, that you both have the same thing in mind. I don't think it is as big an issue as it seems to be.

DR. MONSEES: I would like to hear a response from Ms. Heinlein.

MS. HEINLEIN: I think that Dr. Sickles has summed it up well. I think that the voluntary process could be implemented right away, whatever "right away" might be, in another six months or a year. But it will take a good

couple of years to write regulation on all of that.

I think that just to say there is no controversy over the technologist or the medical physicist, so that makes them ripe, so we will go ahead and regulate them, but there is controversy over the physician so we won't worry about that. I don't think it can be that issue.

I think you are right. You can see what happens as it evolves over the voluntary program and I think that is the better pathway to go.

DR. MONSEES: Did you have a comment, Ms. Hawkins?

MS. HAWKINS: Yes. Coming from the perspective of a consumer, and, certainly, I do appreciate the exemplary personnel of professionals on this board, but having been a person who has been faced with diagnosis and treatment of breast cancer, the urgency of dealing with it did not allow me the time to go out and go through a search for who was actually qualified to work with, to help me face my problem.

I will tell you that the MQSA standards that came out, once we looked at what was proposed, as to what should have been in place, it left many women with many, many questions about how many mothers and sisters had died that, perhaps, should not have died if there had been proper personnel, procedures, and so forth, like that, in place.

So I just think it is very important. When we

think in terms of the impact of breast cancer and the pending impact of breast cancer upon women, the issues of women, that we leave no stone unturned.

So I just strongly urge regulations across all personnel. I think it is very important. One of the reasons I will share with you. I am working on a committee related to trying to improve services and promote independence of older adults in our community.

One of the physicians who serves on this committee--and what we are trying to do, basically, is educate the physicians about how to manage community and home-based care. The cardiologist on the committee said, "Whatever you do, make it simple because the doctor's don't have time to read a lot of things."

So that discourages me that they don't have time to read something about it. That is going to be very important. I also think it is very important to move away from the issue of the average patient. I don't see myself as an average woman. If I did, I would look like most people. I certainly would have more money and be in a better position.

So I just don't see the average woman out there floating around. I see individuals out there floating around who need individual attention. We are not just

dealing with a diagnosis. We are dealing with something that attacks a woman's mind, body and spirit, total person. It just needs much more attention than what has been given to it.

DR. MONSEES: Any other comments on this issue?

MR. PIZZUTIELLO: It is really hard to follow such an eloquent comment with something sort of mundane. But I will say that, in terms of attracting the attention of the community, that is another advantage of developing parallel regulations while the voluntary process is going on.

Nothing gets the attention of anybody like hearing footsteps. I think that if the message comes out to the community that there is a program going on and, if it fails, then FDA will try to figure out if they can regulate it, everybody knows what that translates into.

On the other hand, if they hear that there is a voluntary option, if we can get to very near full compliance, then it will end there. But, just in case that doesn't happen, FDA is preparing regulation to go into effect if people don't voluntarily comply, then we might, maybe for the first time in history, lose this oxymoron.

So I think that is another advantage of the parallel regulation.

DR. MONSEES: Any other comments? Are there any

other issues that we feel that we should consider for regulation, that are ripe for regulation? Now that we have coined that phrase, we might as well use it. It sounds poetic--ready and ripe for regulation. Nothing else?

Okay. Let's go back to NMQAAC questions. We have now covered through 6. Have we covered 7, "If a procedure is to be regulated, what are areas within that procedure?" We think we have. With the mammographically guided procedures, we said should the MQSA certify; major change over what exists now.

Next is no. 8; "Which procedures are amenable to clinical-image review evaluation and should clinical-image review attempt to evaluate the quality of the image or the interpretive skill of the physician?" Let's tie that to 9 with the medical audit for interventional facilities.

I would like to hear the opinion of panel members on this, questions 8 and 9.

DR. HENDRICK: I, personally, believe clinical-image review should evaluate the quality of the image. I don't think you could possibly evaluate the interpretive skill of the physician without a huge number of clinical images being evaluated and having access to the reports on those images. I think it is beyond the scope of what is possible at this point.

DR. MONSEES: So you are in favor of clinical-image review for equipment evaluation but not for physician competence?

DR. HENDRICK: It is a little more than equipment evaluation. It is evaluation of a number of issues in the context of stereotactic including positioning, targeting.

DR. MONSEES: Maybe appropriateness and things like that.

DR. HENDRICK: I don't know about appropriateness--and quality of the images. So it goes beyond just equipment but it certainly doesn't get to interpretive skill.

DR. MONSEES: What about the other procedures that were up on the board before that are mammographically guided; not stereo biopsy but how about needle localization and other things? Do we need clinical-image review for those?

DR. HENDRICK: Sure. Well, I think so in some contexts. My understanding is that if a piece of equipment is included, whether it in mammographic or stereotactic localization, you have to have a clinical-image review. Is that not correct--on that piece of equipment?

DR. MONSEES: The question would be is it the mammographic image or is it the needle-loc image? Let's

talk specifically about breast needle localization. Let's focus on that.

DR. HENDRICK: If it is only used for needle locs, which is the way these--if it is used for mammography, it goes through the mammography evaluation. If it used only for needle locs, then it needs to be evaluated in that context.

DR. MONSEES: Let's hear some comments on that.

DR. DEMPSEY: First of all, if you say that there is a uniform, across-the-board, standard that has to be met that this has to be a mammographic machine that has passed MQSA, my hunch is you won't have anybody saying, "Oh; we are just using this for locs," anymore. That was just a convenient way to opt out of getting it inspected.

In terms of these other things, I think that question 9 with the audit, a really well-done audit--and I must say that Dr. Sickles, along with people like Mike Linver, had done an enormous amount of work showing how audits should be done and how much information you can get from these.

One of the most important things that needs to be reviewed, for instance, with stereotactic biopsy is patient selection. Auditing things--and Dr. Sickles has done a lot of work on looking at people's statistics to try to get a

handle on whether or not patient selection was appropriate or not.

Now, the one thing we don't want to do in this country is increase the total number of biopsies being done, be they open or stereotactic, and drive up the cost of the system. I think that the clinical images can show you did somebody target the thing correctly, did the needle go where it was supposed to go, and all of that.

But the audit, to me, is one of the most valuable pieces of information to know whether what you have done, so far, is medically correct and whether, in particular, your patient selection is correct.

I would also add an editorial comment. We were talking about being ripe. If future meetings are held at the same temperature level, most everybody in this room is ripe after two days.

DR. MONSEES: Okay; we are ready to roll. Next comment, Dr. Bassett?

DR. BASSETT: I would just say that what you are talking about is the positive predictive value for biopsies and that is already being encouraged to be kept by the facilities. I would not separate out stereotactic or anything else from--for example, "Here is the stereotactic; here is the localization," because that is largely due to

preferences of the referring physician.

Some of them will send patients who are likely to have cancer for open biopsy whereas they will restrict the ones they send for stereotactic to the more likely benign cases. We have no control over that so I would say, first of all, that we have to be careful when we use medical audit because it is going to depend a lot on the practice and different conditions and so on.

There are some medical/legal areas that we have already talked about on this committee that are problems, so it should be looked at by the legal counsel in terms of is that going to be accessible to others.

Finally, I would just emphasize, and I think Ed will also, that we shouldn't try to separate out the positive predictive value for the different technologies.

DR. MONSEES: Let's hear follow up by Dr. Sickles.

DR. SICKLES: I am going to address both questions, 8 and 9. As far as clinical-image review, I don't think that we will need, because I don't perceive there is a need, for clinical-image review of targeting for conventional localization. I don't think it is a problem clinically and, as Pete suggested, I don't think it will be a problem in terms of units used only for localization because, once they come under MQSA regulation, they are not

just going to be used for localization.

As far as the audit is concerned, there are many, many complex issues that deal with auditing. I have here a sheet of all the things that I would like to see in the complete audit, but I don't know that it will be practical to implement that just as the FDA has not implemented what I would consider a more complete audit in current MQSA regulations because of legal and disclosure limitations.

Those same things will apply to stereotactic procedures. But, in terms of what will give one the most meaningful outcomes, number one, in terms of patient selection which, as Larry and Pete have said, you need to get the positive predictive value of all biopsies, combined--fine-needle aspirations, core biopsies and surgeon biopsies combined for a given patient.

It doesn't mean you count it twice if she has had a core biopsy and then a surgeon biopsy. It counts once. But what we don't want to see happen is the increase in the number of biopsies without an increase in the yield of the number of cancers.

This relates to patient selection. Unfortunately, in the early development of stereotactic biopsy, many clinicians, many practitioners, radiologists, surgeons, whatever, were overusing the procedure. I think there has

been a learning curve and I think many of these practitioners who were biopsying things that really didn't have to be biopsied have learned not to do it anymore.

But this is an important thing to monitor and, probably, one of the most important things to look at because I perceive this as an area of potential public-health problem.

The issue of the accuracy of the procedure, what is the false-negative rate, how many lesions are not being detected because of sampling error, is a less serious problem in my opinion because I think the literature always, up to this point, has indicated that it is pretty accurate.

So I am more interested in that one.

DR. SMITH: You still need the overall biopsy rate. PPV is not enough because it can vary with the biopsy rate in both directions. If the biopsy rate is changing, then you can look into the different patterns of biopsy for some illumination as to what is going on.

You might see that your surgical biopsy rate is still looking about the same or pretty good, but your big inflation is coming in your cores.

DR. HOUN: I was just going to ask Dr. Sickles if, under a voluntary program, the role of the medical audit may be different from a regulatory program and would it be used

for evaluation and maybe shared. If we were overseeing the voluntary program for evaluation of potential regulatory direction, at some point, could this information from a voluntary program be shared with us confidentially, group data to just show that quality is being achieved and performance is being enhanced? Is that something that could work?

DR. SICKLES: I am not a lawyer and I don't know very much about the law. My concern would be that the voluntary programs, themselves, might be subject to the same kind of disclosure problems that the FDA surely is subject to.

If the voluntary programs could, somehow, be exempt from that in all states, and state law is different in each state--in a voluntary program, I don't think federal law would apply. Then the answer is yes, but I am not at all sure that that is true.

DR. HOUN: The voluntary program right now does collect some outcome data on applications, I think, and numbers of cases.

DR. SICKLES: Complications is not a contentious area because the rate is extremely low. The contentious areas are the data that I have given you. I think you are going to have to listen to the voluntary programs to find

out whether they think they can collect this data and keep them confidential. I just don't know the answer to that.

DR. MONSEES: Dr. Smith just pointed out that, perhaps, if the FDA possessed the data that it would be, perhaps, public information in some way.

DR. SICKLES: But the FDA would get collective data. They wouldn't get individual data.

DR. MONSEES: Is it discoverable? I don't know.

DR. SICKLES: I don't think collective data would be a problem in terms of disclosure.

DR. MONSEES: But maybe the FDA doesn't need the data. If the voluntary program is evaluated in the data and can document improvement, or whatever, maybe the FDA doesn't need to have the actual data.

DR. SICKLES: I don't think the FDA needs and probably would want the individual data. I think they would be much more interested in the collective data to show that the voluntary program achieved an improvement in quality of care.

DR. MONSEES: Do they need collective data or do they just need an answer as to whether there is quality improvement or not?

DR. SICKLES: You can ask the FDA.

DR. HOUN: I can't say right now. I think that

certainly the bottom line would be some agreement on what the performance indicators would be and whether they were actual numbers versus description of improvements. That would be something we would need to discuss with them in terms of overseeing when evaluating their success or failure.

DR. MONSEES: Dr. Smith, do you have a comment on that?

DR. SMITH: Yes. I think that the problem is that individual data may be discoverable one way or another. The issue for the FDA is that they can look at any kind of data that they think are relevant, but once they possess it, once it is handed to them in an FDA building, then it becomes subject to the Freedom of Information Act.

Agencies have dealt with this issue in the past by simply saying, "We are going to look at it at your place and we are not going to take it home."

DR. MONSEES: Obviously, any way to proceed on this would have to be done with extreme caution because this is a major problem that could really, I think, dissuade people from complying and giving accurate data. This is important. If you are going to collect data, you want it to be accurate and you want people to be forthcoming with the correct information.

Any other comments on that about audit? How about clinical-image review? We talked about using it to evaluate the equipment in the practice but not, necessarily, to establish professional competence.

Does anybody disagree with that that maybe it is not possible to do that at this point in time, or it is not appropriate.

DR. FINDER: I had a question to clarify that. One was to evaluate the image quality. Then I heard it wasn't to evaluate the interpretive skill but then there was targeting thrown in, that that was to be evaluated.

DR. MONSEES: That is part of the voluntary accreditation program for stereotactics, that you provide the images showing how you have targeted for either a mass or a mass and microcalcifications. It tells you something about the facility's ability to demonstrate on their best images and I think that is valuable information.

That was your point; is that correct?

DR. FINDER: Okay; so it was targeting included.

DR. SICKLES: I think the distinction should be drawn between targeting for stereotactic procedures, which is important and which is quite different than the targeting for conventional localizations which is not a clinical problem and which, I don't think, requires clinical-image

review.

DR. DEMPSEY: Just for clarification, my feeling is, and I want to make sure we are all on the same page here, things like preopeative needle localization and galactography, to my way of thinking, don't need to be regulated at all. First of all, the number of galactographies in this country is estimated at 4,000 or less.

That is a whole lot of effort to regulate something that is not a big problem in preoperative needle localization. I just think we need to spend our time regulating things that are contentious, if you will.

DR. MONSEES: The equipment needed to be regulated. The only other problem that we identified when we went through the grid was there was a question about excision of certain things. I, personally, would like to suggest that, perhaps, that be addressed as part of the voluntary accreditation program because many of these cases are tied together, just like Dr. Sickles just said.

Biopsies are tied together so that, in describing a best-practice situation or what is suggested, that, perhaps, that be included.

DR. DEMPSEY: I agree with that. But I am just

saying that if you got through the regulations that all mammographic equipment has to meet standards, that takes care of basically the other problems.

DR. MONSEES: Okay. Is there anybody else with comments regarding 8 and 9?

MS. EDGERTON: I would just remind the committee that if you are looking at not having clinical-image review for needle locs that you all seemed to be aghast when I said that that was the only thing that caused these other units to fail. They met their image quality when we did phantoms on them.

They met annual inspections. They met the criteria for their annual physicists reports. The only thing that caused them to be kicked out of the MQSA was they couldn't pass clinical-image review. You all seem to say, "Well, gosh; that is creating a second class of machines and we don't want to do that."

DR. MONSEES: We agree. What we are saying is that any equipment that is used to take the mammogram--not stereo; I am talking about conventional mammogram--would need to pass clinical-image review.

MS. EDGERTON: I thought you said for needle locs, you did not want to see--

DR. MONSEES: We would not want to be looking at

the needle-loc images but that the images that would go and be presented would be conventional clinical images.

MS. EDGERTON: Thank you.

DR. MONSEES: We don't want to have to grade targeting and needle placement. But we do think it is appropriate to look at the clinical images, and they should produce good clinical images.

Does anybody disagree with what I just said? Any other comments on 8 or 9?

No. 10; "Do voluntary accreditation programs currently exist?" We know they do. "Can they be created in a reasonable amount of time?" This is where we need to spend some time discussing a time line here and how can that serve for suggested regulation. If we are going to do the parallel course, let's talk about time periods.

The floor is open for this discussion item.

DR. MOORE-FARRELL: I have a question for the collaborative program between the ACR and the College of Surgeons. When is there a place that both radiologists and surgeons apply? Is that up and running? Can you apply for that now? What is the time frame?

DR. MONSEES: Would you like to comment on that for the record, speaking for the ACR?

MS. WILCOX-BUCHALLA: As a result of the agreement

that was reached between the College of Surgeons and the ACR and agreed to in June by the boards of both organizations, we have incorporated that criteria in the program and surgeons or other non-radiologists are eligible to apply now, whether it is collaborative or independent.

MR. MOBLEY: We have heard different numbers about different things so they may have gotten clouded in my mind, but as I remember, I was thinking that yesterday someone told us that there had been 300 applications to this program currently and 100 had been approved.

MS. WILCOX-BUCHALLA: That's right.

MR. MOBLEY: We think that there is a universe of several thousand facilities out there. What I am trying to do is establish a baseline as to where we are today in terms of if we want this question of where do we want to be a year from now or in terms of the FDA making a decision to go forward with the regulations or not go forward.

So I have my baseline.

MS. WILCOX-BUCHALLA: You have your baseline. I think there are two issues relative to this program not moving as rapidly as some other programs have in the past. Most of the accreditation programs at the ACR are under voluntary accreditation. We see that within the first year or so, we have about 400 facilities participating so this

one is a year and a half old and we only have 300.

I think that is related to people sitting back and waiting to see what is going to happen with FDA because, until this meeting and until very recently, the thought was that it would come under MQSA. People wanted to wait and see what the FDA was going to say they had to do before they jumped in and did something.

The other issue was this issue of agreement between the ACR and the College of Surgeons about non-radiologists being able to participate. I can tell you that at least a couple of times a week, I get a call from a facility, generally a radiologist, who says, "I have surgeons in my facility who also use this equipment and unless we can both apply, we are not going to apply at all."

So now, from my perspective, that issue is resolved. Although we know that there are some things that we need to go back to the table on, I think we will continue to proceed.

In terms of being able to handle the volume, I think that the ACR has always been ready to respond to the issues that have been presented to it. We will recruit additional reviewers and staff as necessary. I think that is probably going to be on the table as soon as this meeting is over.

DR. MONSEES: How can the ACR publicize this beside the ACR Bulletin which is not distributed to surgeons. How would you intend to publicize? Maybe you can think about ways to do that so that people can cooperate or who would like to cooperate will know about it.

MS. WILCOX-BUCHALLA: We will find ways to do that, Dr. Monsees.

MR. FLETCHER: I am not sure who can answer this, but with the voluntary programs that exist now, what is the experience as far as 100 percent participation, over what time period that might be achieved, if you could pick an example.

MS. WILCOX-BUCHALLA: Do you mean in other modalities? Is that what you are referring to, Mr. Fletcher?

MR. FLETCHER: Yes.

MS. WILCOX-BUCHALLA: I don't think we have a good sense of that. In mammography, which is the oldest program, we had about 76 percent application rate before MQSA. I think that is sort of where that number got tossed around a little bit yesterday.

Our ultrasound accreditation program is also relatively new and has not been publicized, really, at all. Our MRI program is brand new. It is six months out of the

box and so that is also--there is no other measure to look at, but the issue that Mr. Pizzutiello brought up about linking it to reimbursement is part of the ACR's strategic plan.

We intend to go to third-party payers including HCFA and others, to have all accreditation linked to reimbursement. That is where you get voluntary compliance, Mr. Mobley, is when you talk to somebody about their pocketbook.

DR. MONSEES: Thank you.

DR. SICKLES: I think we can save a lot of time on this issue by--it is my sense that most people, if not all people, on the panel are comfortable with this parallel-track approach. I suspect that there will be a substantial amount of time to take the FDA to be ready with their part of the parallel track. I would propose that they simply look to the voluntary programs at the point where they are ready and see whether the voluntary programs are ready at that time.

They could probably give the voluntary programs some indication of how long they think it might take them, but that is a necessary part of the parallel track, is the FDA part. Since we expect it to take a year and a half or two years or three years or whatever it might be, then the

voluntary programs will have the fire lit under them.

The people who want to make the voluntary approach succeed will have their impetus to work hard at it. The people who would be complying with the voluntary programs would know what the time line is. I think it is a fairly simple solution rather than a complex one.

DR. SMITH: I don't know what that time table would be. Under the standard regulatory program or, of course, the FDA could announce that it has a new express regulatory program. But what you really want to avoid is what might be called the "April 15th syndrome," which we also had under MQSA, where suddenly there was this mass of flood of applications at the last minute, good-faith gestures, to either avoid a regulatory program or having to shut your door and not offer mammography because you were not accredited.

So I think it would be really incumbent upon the College of Radiology and the College of Surgeons and, perhaps, working with the various consumer groups, to really blanket the country, the surgeons and the radiologists, with direct mail, with copies of the CA article, with notices on the accreditation program, and telling them that this thing is coming.

Offer incentives; "Apply early. Get a break on

your review." Whatever it might take to have this process ratchet up rapidly. Get a personally autographed audit manuscript from Ed Sickles.

MS. HEINLEIN: A question. We have discussed the voluntary program that currently exists through the ACR as an accrediting body. Can any accrediting body come up with their own voluntary program and, if that is the case--I mean, there are other accrediting bodies like the State of Iowa and, I think, California and a couple of other states.

Can they, then, come up with their own voluntary program?

DR. MONSEES: I think we are talking about voluntary programs and, therefore, it is outside of MQSA.

MS. HEINLEIN: So they could do that if they wanted to?

DR. HENDRICK: I do have a concern about what was mentioned yesterday of the College of Surgeons coming up with what they called their own accreditation program but it really involves just physician credentialing. At some point, that issue is going to have to be dealt with that the use of the term "accreditation programs" may be applied to completely different animals in terms of the scope of what they are accrediting.

If that is the accreditation program subscribed to

by the major number of surgeons in this country, I think you have a problem of ever insuring compliance with a voluntary program because all it is doing is looking at one of a large number of evaluation criteria.

DR. SICKLES: There is, of course, the possibility that additional organizations beyond the ACR and the ACS will want to be involved in this voluntary approach. We heard a letter from a physician whose name was tied to another organization. I have forgotten the name of it, but it is a different organization that had different proposals that were what I would think are too lenient.

DR. MONSEES: This was the breast surgeon proposal?

DR. SICKLES: Yes. I forgot what the name of the organization was.

DR. FINDER: It is the American Society of Breast Surgeons.

DR. SICKLES: But they had a different proposal. What I would suggest is that any organization which attempts to put forth a voluntary program should be extremely similar, preferably identical, to the joint program that the ACR and the American College of Surgeons put together because what would be unacceptable would be different levels of satisfaction of credentialing, equipment, whatever.

We need to have this uniform around the country. So although there may be other organizations interested, I think a clear message should be given that all voluntary programs will have to be essentially identical or it is not going to work.

DR. MONSEES: Responding to Dr. Hendrick's question about the ACS voluntary accreditation program, it was my understanding--and, unfortunately Dr. Winchester is not here right now--but maybe Dr. Bassett can help us make sure that we are talking about the same thing, and that was the ACS and the ACR were going to go back to the drawing board and see if they could come up with a conjoint program.

Am I incorrect or correct in that?

DR. BASSETT: I would interpret that a little differently. They are going to go back to the drawing board, try to take into account some of the issues and concerns that were raised here and go back to their parallel equivalent programs. The American College of Surgeons is, I think, set on the path of having their own accreditation program and are not going to be dissuaded from that, from what I understand.

However, the colleges intend to have equivalent requirements in terms of what we come up with and what we consider appropriate numbers of this and that and the

details.

DR. MONSEES: So we look forward to seeing what is drawn up, then, I suppose, between the two.

DR. SICKLES: What I heard from Dr. Winchester was that it was the intent of his college, the American College of Surgeons, to develop a full accreditation program with all of the aspects that are identical to the ACR's program and that they were going to be looking to the ACR to help them in planning and implementing the aspects of that accreditation that they have no experience with; for example, image review, et cetera.

MS. HEINLEIN: Going back, again, to different accreditation programs, since that does not fall under the auspices of the FDA, can the FDA say to these different accrediting bodies that you need to have similar standards?

DR. HENDRICK: It is voluntary.

MS. HEINLEIN: If it is voluntary. You just said it doesn't fall under the auspices of the FDA.

DR. BASSETT: It is clear that if the FDA is not satisfied with what they come up with, then the process will be over if they are going to develop their own. They are very worried about it. They are not stupid. If this process is something that is not going to be satisfactory to groups like this and to consumers, and so on, then the

process isn't going to work. That is why they are trying very hard to get this moving, get some experience, get some development.

Even if it doesn't work, it will be much better for the FDA to come in at a time when there is something that they can see what works, what doesn't work, and so on, than to try, at this point, to set up regulations on issues and problems--we don't even know what kinds of problems are going to arise when these processes go into effect.

DR. HOUN: Just because it is voluntary doesn't mean that we cannot give them very good advice.

DR. SMITH: I think that FDA really does need to send all the groups very strong signals that part of the regulatory process is standards for accrediting bodies and that it would be a shame to really place your bets on one model that wouldn't be sufficient in the end.

The other thing; it is disappointing to me to get a sense that the two organizations could not come together and develop a joint program because that really would provide the opportunity to work out some of the more contentious turf issues and professional issues that we heard yesterday.

David is not here, but I hope that they, perhaps, over time, would still be open to that and, perhaps, the

process of working together might make that more logical. It certainly could even out the workload.

MR. MOBLEY: Having heard the discussion yesterday and today and being a regulator, I guess I would like to put some goals out there. The question is what can be done. There is a voluntary process that currently exists and exists in the a group that has had some experience in doing this.

It is pretty broad in terms that it allows entities, sites, to apply irrespective of whether it is radiologist, surgeon or whatever. Thus, I would put out a hurdle there for people to look at and that would be 75 percent of the facilities in a year and 98 percent plus in two years. If you haven't met those goals in a year, then FDA should continue forthwith.

If you haven't met it in two years, they should be publishing the standard in that final year, at the end of that final year. That, I think, provides incentive. I know there are monetary incentives, but this is faster than monetary. There it is.

DR. HENDRICK: Are you talking about applied or accredited with those target figures?

MR. MOBLEY: Accredited. I had this covered by the mike stand. Accredited.

DR. HENDRICK: Then I think you should just proceed with the FDA program immediately. It is impossible.

MR. MOBLEY: Give me a proposal.

DR. MONSEES: What is doable? Dr. Hendrick, can you comment? Maybe we will ask ACR for a comment, what they think is achievable.

DR. HENDRICK: First of all, you have to accept that the failure rate is probably going to be between 25 and 50 percent. So to require 75 percent to be accredited within one year means everybody in the universe of stereotactic sites would have to apply and, miraculously, 75 percent of them would have to pass within that year.

I think that is unachievable. I think if you had, say, 60 percent application and 40 percent are really accredited within the first year, you would be doing amazingly well.

DR. MONSEES: So amazingly well that you wouldn't put that as a goal? What would you put as a goal?

DR. HENDRICK: I am saying that if you want to set, I think, a pretty difficult thing to achieve, it would be more on those order of numbers rather than 75 percent accredited in the first year.

MR. MOBLEY: The issue here is that, in terms of doing this, in the past, your experience has been with

voluntary programs that were voluntary. I don't know how to talk about this. They were totally voluntary. Now, we are talking about one that is voluntary to the extent that you have got to get it done.

So you have got a driver that is more than, "It is that I want to do this, so I will do it." It is a driver that, "If I don't do this, I am going to have it done for me or to me." My numbers are just, "Here is a number." I can accept numbers that would be more reasonable based on experience, but I want those numbers to be something that is--this is just not the straightforward voluntary thing, but this is a voluntary thing with an impetus to it to get the job done.

So I am going to push your numbers. I am going to suggest 70/50.

DR. MONSEES: The other important point is we only have one program that exists currently. If the surgeons are going to forward their own accreditation program, that is going to give a certain lag time here because they haven't developed the problem yet. So either surgeons will have to apply to the ACR for accreditation or it won't happen.

MR. MOBLEY: May I comment on that?

DR. MONSEES: Yes.

MR. MOBLEY: I respect their desire to develop a

separate program and I recognize, if they want to do that, then certainly they should be given the opportunity. But, in the near term, in addressing this particular issue, there has been discussion about it. There has been coordination and collaboration between the groups. We have a process in place that can address this and it is open to surgeons and radiologists, both.

I think that we can push this and they can either, then, decide to pursue it on their own. Surgeons can pursue it on their own, through their own process and they have the time to do that, but, during the interim, they can pursue accreditation through the ACR.

DR. HENDRICK: Question 11 is do adequate voluntary programs currently exist.

DR. MONSEES: I don't see question 11.

DR. HENDRICK: 10; I'm sorry.

DR. MONSEES: Help.

DR. HENDRICK: I would say the ACR program is an adequate program that exists. The ACS program doesn't exist yet.

DR. MONSEES: It is pie in the sky.

DR. HENDRICK: Exactly. So, in addressing this question, we can only talk about compliance with the ACR program because we don't know what the ACS program--

DR. MONSEES: Right. We would need commitment from the surgeon community to apply to this program, then, since it seems that the time frame would be inordinately long if they were to develop their own program.

Now, let me ask another important endpoint question. If you decided to regulate, when would the 100 percent compliance date be? Maybe would should look at that. If FDA decided to do this, you would have to come up with rules and regs and blah, blah, blah. What would be the date, the soonest expected date or the expected date that we could assure 100 percent compliance?

DR. HOUN: I think that those kinds of decisions really need data. If we set an arbitrary date of tomorrow, we will have massive noncompliance. People will be outlawed. We need to work with the accreditation folks on the mutual date.

DR. MONSEES: Right. I'm sorry; maybe I didn't phrase this properly. If you wanted to develop an FDA regulated program and you decided, say, tomorrow, in the office, that you were going to aim towards that, you would have to develop the regs. You would have to go through the whole process that you did for MQSA.

What would you expect, in terms of the actual day of enforcement, because what we need to compare is how long

it will take the voluntary programs to achieve that as opposed to what it would take the FDA if they were doing this and going to enforce this program.

DR. HOUN: I think that the regulatory process requires some steps. One is that we would ask our advisory committee, you folks, to review proposed regs on this issue. I can imagine this would be more than one advisory committee meeting. And I can imagine, too, that as the accreditation programs evolve--you know, the ACR program just added other physicians, the surgical program just getting started--that standards for accreditation bodies are going to evolve rapidly over this next year as these two become models.

So I think that just discussion of regs for accreditation bodies and for facilities, including equipment, QC, QA, all the new technologies for, as Dr. Hendrick was talking about we would have to adjust, would be at least a year process or more.

After that, we are required to give the public notice and comment opportunity. So we have to publish these as a proposal. That process of publishing as a proposal typically will take from six months to nine months for a draft to go through the clearance process from HHS to be published as a proposal.

It is published as a proposal and, typically, we

give the public 90 days to comment. I am sure we are going to get back hundreds, if not thousands, of letters. We will analyze those comments. We got back 2,000 letters, 800 comments. It took us from July 1 of last year to roughly the end of February to analyze all those letters and comments and start writing draft responses because each comment we must respond to, why the government is going to take the advice or not.

So, from notice and comment publication, at least a year or so to analyze comments, produce another draft--and I am sure you will want to review that. So this process is long.

DR. MONSEES: So we are talking three to four years.

DR. HOUN: Yes. And I also think that when you want to give voluntary compliance a chance, you need to really be realistic. Insurance is going to be a major driver, but to get insurance companies on board, you are going to have to lobby the different--HMOs, HCFA, some of the private payers. That is going to take time.

I also think there is the other strategy of marketing alliances, getting agreements with ACS on your 1-800 hotline, only advertise us, going to NCI, getting that on the 1-800 cancer line, doing all kinds of media blitzes.

It will take a year or more for the public to get educated on accreditation programs which one has not come into being and the other one is rapidly evolving.

DR. MONSEES: The reason I am asking this, for obvious reasons, is that if we have to look at how successful a voluntary program will be compared to if it were regulated, we need to be generous about the time period that we need to give to voluntary programs to get started and to get going here.

If we are talking three to four years, if it were regulated by FDA, then it may be unreasonable to say that in a year we want 60 percent compliance, because we would be better off with a voluntary program with 50 percent in a year than we would waiting four years for 100 percent.

Comments?

DR. SICKLES: The time line with which an FDA program would actually be enforced is quite long, for all the reasons that you have heard. The time line has steps involved. They are well defined steps and the voluntary programs already know--they certainly know because these people are educated people. They know what those steps are and they know that if they are way behind in achieving compliance that the FDA program is going to proceed apace where, if they are way ahead, the FDA program may not.

I don't see this as a big problem. I see this as something where there is cooperation between the ACR, the ACS and any other organizations, and the FDA, because I know, from the point of view of the professional organizations, that they want voluntary compliance to succeed.

They don't want to be regulated. They would like to regulate themselves. They will have to work as hard as it takes and get their members to comply as hard as it takes to avoid the threat of a mandatory regulation. They will know what the end is because they will be talking with the FDA as it goes.

I don't know that it is really a big deal to figure out time lines once the FDA comes out with an announcement that there is going to be a parallel process and it is going to happen.

DR. HOUN: I think we have already made that announcement in our joint article with Dr. Finder in the American College of Surgeons Bulletin. We said that while we are undergoing this regulatory process, which includes all these meetings, we are encouraging the professional societies to develop their practice guidelines in that we can learn from that.

So it is easy for us to just adopt many of the things that are going to be tested out in the voluntary scene.

DR. SICKLES: What I would like to see from the FDA is more than that. I would like to see a definitive statement that there is a parallel track system underway now and that it is going to take time for your aspect of the parallel-track system to kick in and that, therefore, there is a defined time in which voluntary regulation can succeed, that the organizations know what this time line is and the clock is already running. I don't think that message is out well enough, certainly not to the radiologic community and I doubt it as to the surgeon community.

I think that has to be definitively stated, very clearly.

DR. MONSEES: It is, according to the agenda, close to lunch hour so I will hear these two and then we are going to adjourn for lunch and then reconvene.

DR. SMITH: I just wanted to echo Ed's point that you could put notices up through Stuart Nightingale's office and on the web page. There are lots of different routes. But the other thing is that once this process--I mean, a four-year process is one thing. But once you finish the regs and you put them out for public comment, you can't

continually do this under the banner of "We still might not do this in the end."

There is a point at which your foot is in the river. So the voluntary programs really are going to have to send a signal that we have really got to be moving quite, quite fast because otherwise we will reach the point of no return, I would think.

MR. PIZZUTIELLO: I also agree that the numbers need to move sort of slowly. I think it is really almost a four-year process to be sure, after the regs get published, they usually don't take effect immediately. So if you think in terms of four years, simple numbers like, maybe 50 percent in two years and, I think, if you talk about facilities that are actively in the process.

I would prefer not to differentiate between those who pass and those who haven't passed, and give two percentages. It is too complex. If facilities are actively in the process, they have paid their money, they are trying--even if they have failed, they have paid more money. They are sort of committed to making it work.

I think that, for this level, that would be a simpler way to approach it.

DR. MONSEES: Concordant with that would be the hot-line information of approved programs which would give

further incentive to people to move along.

Unless there are any other pressing comments, I would like to adjourn for lunch. It is possible, if there are no other issues that come up, that we actually could be ahead of schedule because we are not going to be examining needle loc, fine-needle aspiration, cyst aspiration, galactography, as on the previously published agenda. The way it has been evaluated now, I think we are pretty close to closure on that.

So it is possible that the states as certifiers update may be early. If you are waiting around for that particular thing, please be advised to come back after lunch because it could be heard earlier than on this agenda.

With that, we will reconvene at 1:30 for this afternoon's session. Thank you.

[Whereupon, at 12:25 p.m., the proceedings were recessed, to be reconvened at 1:30 p.m.]

A F T E R N O O N S E S S I O N

[1:35 p.m.]

DR. MONSEES: We have something that is going to be read into the record by Dr. Finder to start with. I will let him tell you what that is.

DR. FINDER: We got a request from several people in the audience for the medical audit as promulgated by Dr. Ed Sickles to be read into the record. So what I would like to do is just read this.

It begins by, "Calculate for the entire practice." And then, in parenthesis, "And for individual radiologists if there are a sufficient number of cases. One; complication rate, especially if treatment is required. Two; repeat biopsy rate," and under that, there is, "Technical failure or equipment malfunction, improper targeting, inadequate tissue sampling, discordance with image findings, ADH, radial scar, et cetera.

"Number three; follow-up compliance rate. Four; appropriateness of case selection." Under that is, "PPV of percutaneous and surgical biopsy. Five; effectiveness of reducing benign biopsy, PPV of surgeon biopsy. Six; accuracy." Under that was, "Sensitivity and Specificity."

Did you want to add anything Ed?

DR. SICKLES: No.

DR. MONSEES: This is pertaining only to biopsies. Your follow-up compliance rate; what does that mean? Follow up meaning coming back for their next mammogram or follow up to have surgical biopsy?

DR. SICKLES: What I meant there; follow-up compliance meaning that if, as a result of the stereotactic breast biopsy, a recommendation was to come back in six months to see that things are stable, what percent of those women actually did come back in six months.

At this point, I would like to open to the panel the opportunity to discuss any other issues that are lingering, give people an opportunity for comments, clarifications, any other issues that we should be addressing today.

MS. HEINLEIN: Throughout our entire discussion this morning concerning interventional procedures, I am just assuming that all of the parallel pathway here would apply to stationary as well as mobile stereo sites. That is something to think about because there are, now, mobile vans that have stereo tables in them that are traveling around to different hospitals.

So I just throw that out as something else to think about.

DR. MONSEES: That seems appropriate to me. Does

anybody disagree with that? Okay.

MR. MOBLEY: I want to close on this issue about the voluntary track, the regulatory track. I will close on the issue in my mind since we probably can't close on it as a group. We heard discussion that the regulatory track could take as long as four years, and that is probably not necessarily out of line although I think that there could be some time shaved off of it.

Anyway, we also heard earlier in our meeting that the voluntary track, one could proceed more swiftly and, in fact, that a voluntary track was in place and had been in place for some time and now there is agreement between the surgeons and radiologists which makes that voluntary track equally applicable.

So I think that it is not unrealistic to think that that track could proceed forthwith and, in two years, we could see something there. Based on the discussions of this morning, I am going to propose something that, in my mind, is sort of the ballpark I am looking for in terms of where I would think the voluntary track is proceeding adequately versus not proceeding adequately.

I think that if, in a year's time, 70 percent of the facilities have applied and 40 percent have become accredited, that is a good indication. If, in two years, we

have 100 percent applied with 95 percent accredited, I think that is an excellent indication and that, then, we could take stock of where things stand regarding the regulatory track.

DR. MONSEES: Any other comments on this?

DR. HENDRICK: Just that I didn't hear such great agreement between the radiologists and the surgeons as evidently some other people on the committee. The one thing that they were supposed to agree on was credentialing of the physician. I heard a lot of back-pedalling, actually, is what I heard.

And I heard that the surgeons had been mandated by vote to start their own separate accreditation program so the likelihood of them actually applying as surgeons to the ACR program, I think, is probably going to be forestalled by the anticipation of their own accreditation program without the acknowledgement or the recognition that they are two completely different animals in terms of comprehensiveness.

So I am a lot more pessimistic about everything being copacetic and moving forward rapidly especially in the surgery area of stereotactic use.

MR. MOBLEY: I will agree with his assessment. I just know that many times, to get things going, you just have to lay down some criteria and say, "Here it is," and

that will assist people in doing what is necessary within reasonable time frames. That is my intent here. I think that we see that there is something in place that can go forward, and here are my expectations.

MR. FLETCHER: I think that Dr. Smith brought this up earlier, but I am concerned about the likelihood of the Food and Drug Administration pursuing the development of regulations with no commitment to actually publishing those regulations, being essentially held in abeyance while watching the development of another program.

Perhaps Dr. Houn could answer it because I am not sure to what degree that is possible.

DR. HOUN: I know that one of the several executive orders Clinton signed in 1993 advises all regulatory agencies to first seek non-regulatory means to achieve an end. So we are encouraging professional societies to address problems and take care of them.

I think this problem in requiring us to work together and for us to work in divising a regulatory program, we are committed to doing that because I think what we are waiting to hear--one was scientific standards on equipment, personnel, quality control.

We were also waiting to hear more about the public-health problems that exist. If there are major

public-health problems, you are right; we can shave off the time frame to get this out there to protect the public. The way I am gathering information these last two days was that there is still a lot unknown about these procedures in terms of who is doing them, what is happening, what are the problems.

Infection control may not be a problem. Complications appear not to be a problem. The problem is, maybe, lack of patient communication. Some of those things can't be handled regulatorily so I still think we are in information gathering as well as wanting to work with the professional societies in trying to address existing issues that have already been presented to us like the concern that unqualified people such as receptionists may be doing this.

I don't think there is any evidence, but the potential certainly does exist that unqualified people could be doing this procedure.

DR. SMITH: I am glad we are actually revisiting this because Roland's remarks have raised some other issues as well. You do not have, on this panel, a group of people who are going to be able to come to you with a lot of anecdotes about dreadful situations. They are all doing very good work.

We heard from Malee Shay at the last meeting a

year ago. We heard a number of patients talk about less than satisfactory outcomes with a new technology that is supposed to produce better outcomes.

So it seems to me that what is really missing in this process is a very concerted plan to gather data to inform this process.

DR. HOUN: The data gathering that FDA does is through medical-device reporting and MedWatch. Some of it is mandatory on the medical-device reporting and some of it is voluntary reporting from physicians and health--so we have databases. We have looked at them.

We don't see the numbers of adverse events happening with this related to anything that MQSA can assist in. We have a couple, in probably 250 reports, of which the majority deal with needle shaving problems. Those are device problems that our Device Office has already addressed.

So, in terms of a public-health problem, we don't get reports on inadequate physician communication. That is probably something that complaint boards from medical licensing state departments may get.

We are hearing that there is an equipment problem. Some of the physicists have given us anecdotes of what they are encountering in their experience. In terms of other

information, I know the states want to gather information on this. I think CRCPD has the Mammography NECS Committee and they are interested in doing a survey on this procedure.

So they are going to be gathering information. We don't fund research endeavors so we cannot give seed money to help us conduct the studies. We have already put out that we are interested in information and we have asked other agencies to help us gather this data.

We are encouraging other societies to encourage their researchers to provide this information as well.

DR. SMITH: I understand that that may be all that you can do. The standards of practice are evolving, but they are evolving according to two separate tracks, that it is not entirely clear that, even though the people who work together to formulate these standards, they are working together and talking to one another.

But we heard, at the last meeting, quite a lot of protest that they shouldn't have to work together and they don't need each other. One group referred to the other as an ancillary professional in the process and the other group referred to the other one as an ancillary professional in the process.

So I am having a hard time seeing how all this is supposed to be coming together. It seems to me that we are

building in a lot of inertia. Can you give us some insights as to how the FDA plans to pressure the professional societies about their need to do something and their interest in seeing whether a voluntary solution can evolve?

DR. HOUN: I guess, for me, it doesn't seem that complicated in that I think they already feel the pressure. They have been pressuring us to do more regulatory--we have been pressuring them in terms of getting the surgeons to talk more with the radiologists.

There has been a lot of pressure. One year ago, you are right. Nothing was together and now they have come up with several documents, major publications, about a joint effort. The plan is that FDA will respond. We just got, this past week, the letter from both ACR and ACR saying, "FDA, let us have a voluntary period to see how these programs go. Do not regulate us and let's see what voluntary measures--what success they will have."

We have to respond to that and part of the response will be advice we will give them on what we think will be satisfactory as part of their program which will include many of the suggestions the advisory committee has here on how they may best alter the agreements such as having a consumer-complaint mechanism in place and maybe teaching different courses that were mentioned previously.

Give us more details on--when you say you want to monitor progress of the success of the voluntary program, we can suggest what we would say as good ways to monitor. We need to hear from them what their plans are for monitoring. So the exchange is going to happen to encourage them to continue working together on this.

The other thing we got from the recommendation of the advisory committee today was to go forward with regulating certain parts of interventional mammography such as the use of conventional mammographic units for localization, ductography, et cetera.

We can go forward with that as evidence to the other voluntary programs. "Look; we are going to make a step into regulating interventional mammography. We may allow you this opportunity for stereotactic to go on a voluntary track, but the other interventional stuff has been advised by our advisory committee to pursue."

So those are all signals saying you have got to keep working on it.

DR. SMITH: All that is good. I think that is what a lot of the committee would want to hear.

DR. HOUN: That is the way we are thinking. It is a very evolving process and a lot of people are involved. They are all really hard working and well meaning and have

had backgrounds in having successful programs. So that will continue.

DR. SMITH: There is no suggestion to the contrary.

DR. HOUN: Okay; there is a plan.

DR. HENDRICK: Florence, as part of this sort of voluntary approach, is there any chance of having MQSA facility inspectors noting how many stereotactic units or add-on units are available at mammography facilities and whether they are used or not when they do their facility survey?

DR. HOUN: I don't know. I would have to ask general counsel. It is not an area we regulate, so we typically cannot collect--especially, we don't want to subsidize the inspections which we have a fee for to collect data that is not an area that we are regulating. So I would really have to ask that.

There are other ways we can try to collect the data. The add-on units, I think, are going to be a hard thing to do but I think if we are going to regulate the conventional units, the add-ons are not going to be a big deal.

But finding out the denominator for prone stereotactic is not unsolvable. If we can't do it by

inspections, there are probably other ways to do it using state information, using a combination of other sources.

DR. HENDRICK: But I do think that would get at the biggest part of the denominator and, probably, the most efficient manner, in a uniform manner.

DR. HOUN: Asking 250 inspectors to go into the 10,000 facilities to look for this is a big deal. It would take a year's time as well.

DR. HENDRICK: But by the time scales we are talking about, that is appropriate.

DR. HOUN: I am sure there might be easier ways to do this.

DR. FINDER: The other thing I just want to add to that is that we would probably end up missing all the units that were in surgical offices where we don't inspect at all. So it would be a biased sample.

DR. MONSEES: That's correct.

DR. SICKLES: It may be that the professional organizations, the ACR and the ACS, can come up with creative ways of developing this information themselves.

DR. HOUN: Certainly, FDA can work with that and give what we have, information, to them.

MR. MOBLEY: I just want to address that last issue. I am trying to remember specifically regarding the

MQSA inspections, but I know there is a certain question or something that you look into regarding the follow up of patients. So if you have a finding during a screening mammogram, the patient is referred and the facility is expected to do a certain amount of follow up, I would think you would know what facility--well, you have to know if you are going to do the follow up what facilities people are referred to or where they go to and then follow up with that patient to--oh; you don't? Okay.

DR. FINDER: I would say that the way that we run that audit question, they just check with the facility to make sure that they have that system in place. Now, the facility may not know where this patient is ultimately referred to in terms of a stereotactic biopsy. They may just know who the referring physician is.

And there would be a whole bunch of questions that you would have to ask in order to get--

MR. MOBLEY: So it is not that easy.

DR. FINDER: It is not a trivial matter.

MR. MOBLEY: Okay; thank you.

DR. MONSEES: I would agree. In our tracking, we find out, basically, from the primary-care physician or the surgeon, what the diagnosis is because we are interested in finding out what the pathologic diagnosis is and how the

patient is treated. But we do not collect that kind of information as to what kind of unit was used or--it is not here. I think that would be very hard to get.

Are there any other comments on this particular topic? Are there any other questions or comments regarding anything over the last couple of days that are lingering? Any last-minute thoughts before we move on to hearing this other presentation about states as certifiers? Anything else? Now is the time.

MS. HEINLEIN: May I ask a question? This has nothing to do with protocol or anything, it just has to do with committee business. There are a few members on the committee that did not receive the travel voucher or the expense form. We need to make sure that that is taken care of.

DR. FINDER: Can you give me a list of who is missing what and we will see that they get it faxed to them.

DR. MONSEES: The other thing that I was going to ask, now that we have a couple of minutes to burn, in terms of the parallel track, this is a small group and we are intimately involved with each other. What I am wondering is is it your conception that the same group might be working on the proposed programs for voluntary and regulatory or do you think we will have two separate groups maybe thinking in

two different directions? Do you have any idea about how to work that?

DR. HOUN: I think that the voluntary group is under no obligation to take advice directly from FDA or from any other group unless they wish to.

DR. MONSEES: How about the converse; that is, the people who are advising FDA about its parallel track are probably going to be people that are working on the voluntary program.

DR. HOUN: We seek and want the advice of our advisory committee as well as anyone else who is going to help us do this well. I am sure they feel the same way in terms of the voluntary program. They are not trying to develop a program that is going to be not acceptable to FDA at some future date.

So even though there is not an obligation, we have shared materials. We are going to be giving back comments. Eventually, when it comes to the regulatory process for, like, accreditation bodies and facility standards, we will, again, ask our advisory committee at that point, "What are the standards for operating physicians?"

We will, again, have the voluntary people present, probably, a new version of this. Those may be acceptable in that future date or there may be a continued discussion.

The voluntary people have a lot of listings of what they think the person needs. Maybe as a regulatory institution, since we want to have minimal quality standards, we don't to have the maximum, we may not want all of these.

So I see there will be some differences but I don't think they will be major ones.

DR. MONSEES: I would like to thank everybody for participating in this process over the last two days. You are an incredibly cooperative group. Excuse me; I know I am new at this and I have probably been a bit abrupt at times. I apologize for that. But thank you very much. You have been wonderful. I even look forward to the next meeting, whenever that is going to be.

The next item on the agenda is an informational item. It is really not up for discussion on the agenda although if there are some questions, I think we can entertain those. This is Ruth Fischer who is going to be talking about states as certifiers. She is the Acting Chief of the Mammography Standards Branch.

States as Certifiers: Update

MS. FISCHER: I am glad we can now turn our attention to an issue over which there is complete agreement and absolutely no controversy, states as certifiers.

For the new members of the panel, I would like to

give you just a brief overview of what this issue is about. We have had two presentations to the advisory committee, one in September of '94, one in July of '96. So there has been a lot of background and preparation already given to this, but I would just like to call your attention to a part of the statute that hasn't had, really, very much attention paid to it up until this point.

If you look at your statute, it is subsection Q.

[Slide.]

What this is about is FDA operates as a certification body. The accreditation bodies carry out the quality standards. Facilities apply to them. They check credentials. They check the machines. They check the QC programs and so on that you are all familiar with.

They then transmit data to us on the facility saying whether or not they were granted accreditation or denied. If they are granted accreditation, we follow up with giving them a certificate. So the initial screening for all facilities goes through accreditation bodies.

When they come up for renewal, once again they go through the accreditation process. The certification process has a few components to it besides issues certificates; the inspection program, the yearly inspection program, is under certification activities. The issuing of

sanctions is a certification activity. Ultimately, suspending or revoking a facility's certificate is a certification activity.

There is a close working relationship between the accreditation body and the certification body. We now have four accreditation bodies. Of course, you all know who they are. One certification body is FDA.

This section of the statute, which is not yet implemented, allows qualified states--and I must emphasize "qualified;" this is not free-for-all and it is not an entitlement--but qualified states can share in FDA's certification activities. We can delegate to the states certain responsibilities.

The delegated authorities are; the issuing and the renewal of certificates--this does not interfere with the accreditation process; the suspension and revocation of those certificates; the annual inspection program; and the issuing of sanctions.

So in the area, for example, of sanctions, what this could mean is that there could be different penalties depending upon location. Instead of FDA issuing certain monetary penalties, they could be tailored for local or regional areas.

[Slide.]

This is further complicated in that FDA retains dual authority in the following areas; the suspension and revocation of certificates; issuance of sanctions; and injunctions. So what does this mean? This means that if, under a state certification body, a facility is performing badly and they issue a penalty, FDA may find that it wants to also issue a penalty. So there is dual authority in these areas.

[Slide.]

The areas which are not delegated are; the approval and the withdrawal of approval of accreditation bodies; the establishing of quality standards anywhere along the way in MQSA--so, for example, not only the final regulations but anything that happens on interventional, anything that eventually happens with digital; that is all retained; the collection of fees; and the approval and the withdrawal of approval of any of the state certification bodies. So those still remain FDA activities.

That, basically, is what is outlined in the statute. The history on some of this development is that the Nuclear Regulatory Committee has had an agreement state program for over 30 years. It has had a lot of oversight by the General Accounting Office as well as Congressional inquiries.

They have changed their program very dramatically in response to inadequate federal oversight charges, in response to inconsistent data collection from the federal program versus the state programs, and they have developed a performance-based model which has been operational for the last two or three years.

Is that right, Roland? About that long?

MR. FLETCHER: Yes.

MS. FISCHER: We have studied this model very carefully because it most closely parallels the situation for MQSA. We have had a working group established to assist us in preliminary development. This started out being a working group of eight states. There was special regulation promulgated by FDA at the end of 1995 which allowed us to talk to states in this manner and get some input from them.

The states that were selected were the three accreditation bodies, Iowa, California and Arkansas, as well as a representative from each FDA region. So that included Florida, New Hampshire, New Jersey--surprisingly enough, those two are in different jurisdictions; And I would like to point out that the current share of CRCPD is from the state of New Jersey. That is Jill Lipote--Nevada and Illinois.

We have held three meetings. For the past two

meetings, we have been able to have the ACR participate as a working-group member and we anticipate that we are going to continue in this manner so that we have all of the parties present to work this out.

The last meeting we held was in September. It was a two-day meeting. I think we can safely say it was very productive. It was also very collaborative. There was quite an exchange. Among the accreditation bodies and the other state representatives, I can say that the three state accreditation bodies told the other states--and have, in public forums--that this is not a simple process.

You may think it is simple. You may think it is easy. It is not. They know from their experience what the problems are in transferring data, in many operational aspects. So what we decided on was a demonstration program. This would occur before there were any regulations.

This would be a testing out, a working out, on a pilot basis. So the performance indicators that we talked about to the committee before could really be summarized under the following concepts; legal authority, meaning that the state must have legislation and regulation which is parallel to MQSA. This, in itself, is a self-limiting factor.

Just as the federal government takes a long time to develop regs, there are not that many states who are able to put them through quickly. There are a few but they are certainly not the majority. A state must have MQSA regulations in place in order to be able to participate in this program.

Conflict of interest; we are going through this very carefully to make sure that there are no personnel issues, no financial, commercial issues, among any of the certification staff which would preclude them from participating in the program; technical staffing and training; the inspection and compliance activities; and the certification activities.

[Slide.]

The common performance indicators are technical staffing and training. By common performance indicators, we are talking about a performance-based approach in which we are going to evaluate ourselves as well as the states on how well we perform.

For example, there would be a standard for completion inspections in which we establish what the standard is for all certification bodies and then we monitor our progress concurrently to make sure that all certification bodies are on schedule with completion of

inspection activities.

This application and evaluation criteria are going to be very closely monitored throughout the duration of the demonstration program. Typically, a program like this lasts two to three years. We project having a pilot state or states ready to start by next summer.

The feedback mechanisms that we will use will include accreditation body input, our own oversight, state input and we are looking for facility input, also. One point that was made by the ACR is that this should be as seamless as possible. The facility should not be caught in the middle of changing a certification body, should not be confused that standards are different because there is a different certifier.

Now this, of course, is going to require quite an educational campaign, too. Consequently, it is going to be handled on a small basis. Even if a state is approved for the demonstration project for one year, if there are problems, they are not guaranteed. They are not entitled to stay with the program for a year.

It can be terminated if it becomes particularly problematic. Now, we know, in the start-up of anything, there is going to be a lot to work out. But, by keeping it small, keeping it focussed, by having ongoing monitoring and

concrete evaluation criteria, we hope to learn what works, be able to change what doesn't, before we set this down in regulation and open it up to all of the states.

So that is what we are proposing at this point. This demonstration effort has the support and the input from the Office of the Secretary of Health and Human Services as well as the Commissioner of FDA. So it has really very high-level involvement. We will be certainly monitored at all appropriate levels.

So that, in a nutshell, is where we are in states as certifiers.

DR. MONSEES: This is informational only but I will entertain some questions about this. If we want to hear more about this or have this as an agenda item, we can place that on the agenda for future meetings. We don't have the time today to do that.

Do we have a question about the problem?

MS. HEINLEIN: And a clarification. You said that, I guess, the states that will be participating in this demonstration project, that they must have MQSA regulations in place. Doesn't everybody have that? I don't understand what that means.

MS. FISCHER: In their state regulations, they have to be parallel.

MS. HEINLEIN: So you are saying that--

MS. FISCHER: See, right now, all of the states are under contract to inspect. But their state laws may not be consistent.

MS. HEINLEIN: Oh; I understand. So they would have to take the MQSA regulations and incorporate those regulations into their state regulations.

MS. FISCHER: Yes.

DR. MONSEES: I was going to ask a question, too. But I will go with these gentlemen first.

MS. FISCHER: I know I have to answer Ed and Bob.

DR. HENDRICK: Mine is very simple. Can they, as states applying or being certifying bodies, exceed MQSA regulations? Can their state regulations exceed MQSA as long as it is consistent?

MS. FISCHER: Yes; because that is covered by subsection M of the statute.

DR. SMITH: Actually, at a minimum, they would have to be equal or exceed the parallel tracks; right?

MS. FISCHER: Correct. They also have to have the ability to--if it starts next summer, they have to have the ability to have the interim regulations in place and the ability to change when the final regulations go into place. Many states do not have that ability.

DR. SMITH: A couple of questions. First of all, this direction of, in a way, decentralizing--and it sounds like not totally decentralizing but somewhat decentralizing MQSA--that began with several states becoming accreditation bodies and now is moving in the direction of states becoming certifiers, what problems or needs does this solve?

In some ways, what is gained by this?

DR. HOUN: I think when President Bush signed this into effect in October of 1992, in the signing document, he wrote that he is allowing this to occur, state programs to occur, to allow states the ability to escape--I don't think the word was "federal tyranny," but it was something like that, provided that the state was able to assure the standards that would be as tough as the federal ones.

So it is to allow state to not be under federal government if they can do the same thing. That is what the President used as his rationale for signing this into law. That is what I am thinking they are gaining. They are hoping to gain the move to make government smaller, to have state government work in areas of public health.

They are hoping, I would imagine, that the fee and some of the cost for the program would be smaller, too, at a local level.

DR. MONSEES: I was going to ask one. What was

the rationale, and is there a financial incentive, for the states to be doing this, for the individual states to be applying to be certifiers? Is that the reason why states are moving ahead with this?

MS. FISCHER: I don't think there is a financial incentive to the state because they don't benefit. Their own program doesn't, necessarily, benefit from that. I think the financial incentive is to lower the cost to their facilities.

DR. MONSEES: So they would pass along a lower cost to the facilities?

MS. FISCHER: They would try.

DR. MONSEES: I don't know what is going on in other states, but in our state, we are not only paying the FDA but we are also paying the state to inspect each unit. So it is actually higher cost than FDA alone. So I am wondering whether or not this is going to save us money or not.

The other question that I have pertains to the certificates. There is a lot of promotion about being an FDA-certified facility. If you now have states as certifiers, are they going to hand out FDA certificates?

MS. FISCHER: No; they will hand out state certificates.

DR. MONSEES: I wonder what effect that would have on the public feeling about--

MS. FISCHER: One of the things we have been talking about is trying to keep certificate design the same so that there is a recognition for the woman that doesn't--

DR. HOUN: Right; when we designed the FDA certificate, there were blank spaces there that we would encourage states to put their names on and remove FDA. There is a blue band that we would hope the state logo could go on that blue band. There is a lot of space on that blue band.

So there was some thought about having the ability to make it fairly similar although not exact.

DR. SMITH: I have a got a number of questions but I will just come back to this other thing. It is always a little troubling to me when we hear about all the different motivations for passing the law which became fiercely political in the final moments.

We actually, in crafting this legislation--all the people involved really looked forward to a new era of public/private partnerships, collaboration and division of labor continuing from a trend that had been evolving from the agencies and the ACR, CDC, FDA, NCI, HCFA, all of them working together. So we didn't view it as tyranny at all.

There is some way to modify that word, but I am not going to do it for the record--tyracanical?

DR. MONSEES: Does this qualify as a question or a comment?

DR. SMITH: I am leading up to this because what I am wondering is there a disadvantage to the states. If a state becomes a certifying body and, suddenly, the state economy gets into trouble, everything up to MQSA--one of the biggest problems with the state programs--and the people on this advisory committee now have been in this thing for years, knew that there were, oftentimes, very smart and dedicated people in the states, there were state laws, but they didn't have the people to inspect.

They couldn't inspect at the intervals. They couldn't support the program that was in place. So it is actually a technical question; is there any way for the fortunes of the local support of this program to get into trouble because the state has separated from the FDA in a way of having the regulatory control locally.

MS. FISCHER: It really becomes FDA's responsibility to insure that, as part of the application process and ongoing continuation, that there are sufficient state resources. Now, the state has to demonstrate that to us, that they have the commitment and the resources to carry

out the program.

We will probably look to, again, the NRC model, having either governor commitment or high-level cabinet commitment to the program and, once again, to keep on a very small demonstration basis will also be educational to other states as to what direction this is going.

The fall-back position is always if there is any problem, FDA, once again, steps in. The idea is to not have a state dabble in certification but to be fully prepared and qualified to take over that serious responsibility.

DR. SICKLES: To that end, although one possible outcome of having states act as certifiers is they could lower the cost to facilities. I suppose it is possible that states might view this as a way to increase their revenue and increase the cost substantially to providers. Or is that not allowed? If it is allowed, would FDA step in at some point if they felt that this was inappropriate?

MS. FISCHER: The submission of their fee proposal would have to come in to us. It is certainly possible that, under local circumstances, the fee might be higher in a particular state, like Alaska, let's say. However, it all falls under FDA oversight.

DR. MOORE-FARRELL: I know in the state of Arkansas, which is one of the accrediting states, facilities

can be accredited either through the State of Arkansas or through the ACR. Would that option continue in the State of Arkansas?

MS. FISCHER: Yes.

DR. MOORE-FARRELL: And then would some places have an FDA certificate and an Arkansas certificate?

MS. FISCHER: No. If your facility was accredited by ACR, you would get a State of Arkansas certificate as well as if it were accredited by the state.

MR. FLETCHER: Just a comment. In discussing various things with various state program directors, I can virtually assure you that it is a lot more difficult for a state to charge more than the current fees than it is the way the fees are now. It is very difficult to get increased fees for any purpose other than the purpose that you are using it for.

I know that is true in Maryland and I have discussed this with many people who are members of the CRCPD. It is just not something that is easy to do. So I would venture to say, there is probably no state that could increase these fees for their own benefit.

DR. HENDRICK: I assume it is okay--in your pilot, will you have some states that are accrediting bodies and some states that are not accrediting bodies as certifiers?

MS. FISCHER: It all depends on who applies.

DR. HENDRICK: Then I am trying to project, say, five years down the road. Let's say we have half a dozen accrediting bodies and the FDA in, say, five states as certifying bodies and a new modality gets introduced for mammography, say full-field digital. How is that going to work?

MS. FISCHER: The accreditation might be limited. For example, if one present accreditation body were not equipped to handle digital, it may be that they would have to seek, instead of state accreditation, national accreditation. We are going to be starting discussions with all of the ABs in the next couple of months to address exactly what is going to happen when digital comes down the line.

Once you are a certifier, you certify the whole thing, not just parts.

DR. HENDRICK: But I can understand how this body would have the time and resources to develop standards for certification of full-field digital systems. It is not so clear to me that other certification bodies would have the skill or resources or--

MS. FISCHER: They wouldn't be because the establishment of quality standards remains with FDA.

DR. HENDRICK: So those certifying bodies would just take over whatever standards FDA developed.

MS. FISCHER: Yes.

DR. HENDRICK: And you would use whatever accreditation programs were capable of accrediting in that area.

MS. FISCHER: Yes.

MR. FLETCHER: Actually, the last part was what I was going to say. If this program is designed to mirror the agreement states program, the federal agency does not get out of the process. It remains in the process so if something new is developed or, perhaps, even a new procedure is developed, the federal agency would require that any certifying body or any agreement state has to incorporate that in their program within a certain period of time.

MR. MOBLEY: I have been aware of this, but how, exactly, it would come down is a little new to me and I have some real concerns. One is the dual authority. This is maybe peculiar to Tennessee, but we have had dual authority program--not a radiation program--but we have had a dual-authority program at one point in time years ago and it was an unmitigated disaster for the State of Tennessee.

MS. FISCHER: By dual authority, Mike, it doesn't mean that we would be doing double inspections or something

like that. We would probably exercise that dual authority in rare instances when we saw that there was a major public-health problem with a particular facility.

MR. MOBLEY: I can understand that and I certainly believe, given the professionalism I see within FDA, that that would be the case. But we certainly have the history, in Tennessee, of that not being the case, of where dual inspections were done right behind the state inspections and the facilities, as a result, got state citations, federal citations. Unmitigated disaster describes it best.

Compatibility; you talked about the agreement state program as a model. In the agreement state program, the Nuclear Regulatory Commission relinquishes its authority in the state and the state has full and absolute control over those activities in its state as long as it remains adequate and compatible.

This is very different and, in fact, I would see it as being--it seems like it is going to be much more specific in terms of what a state can do and there is not going to be much a state can do that is not going to be dictated.

DR. MONSEES: I am going to cut you off there because we are getting into debate, now, and discussion when this is an informational item.

MR. MOBLEY: Just one other comment, and it is informational. This relates to the question about fees.

DR. MONSEES: What I would like to do is, after you make this comment, to give people an opportunity, show of hands, as to how many people would like to see this on the next agenda for more discussion. So if you want to ask a question or make a very brief comment, go ahead.

MR. MOBLEY: I would just make a comment on fees. One of the things you have to be very careful of in a state organization is yes, you can charge fees if your legislation allows you to charge fees. Sometimes, it is not so easy to recover that fee from the general fund to expend it on the program for which it is that you charged the fee.

It gets very, very tricky and it just makes this whole thing--it is going to have to be crafted very carefully.

MS. FISCHER: Right; that is one of the reasons we are going very slowly. I would just like to make one point to the committee. Under MQSA, we do not relinquish authority. That is not in the statute. FDA does not relinquish authority.

DR. MONSEES: Thank you very much.

I would like to see a show of hands for people--raise your hand if you would like to see this on the next

agenda for discussion.

[Show of hands.]

DR. MONSEES: Thank you. Did you make note of that?

DR. FINDER: Yes, that a lot of hands went up.

DR. MONSEES: I think that concludes the agenda except that Dr. Finder would like to talk now about future meetings. I will let him close out the meeting.

Thank you very much for your attendance, for your contributions, and all of that and farewell to the individuals who will be signing off this committee.

Dr. Finder is now going to talk about future meetings and make any other announcements, and then we will adjourn.

Future Meetings and Concluding Remarks

DR. FINDER: For those who have been wondering what is in the box, it is the final regulations. I don't believe we have enough copies for everybody out there. I hope we have enough copies for the committee, at least.

I will say one thing. I have had a chance to very quickly go through this. It is a rather large document. I will say this to people are getting worried about all these regulations, only a small fraction of this document represents the regulation. The vast majority of this

represents the preamble, the explanations to all the comments that we got, the 8,000 comments.

So I will hand this out as soon as we finish with the future meetings.

DR. MONSEES: Is that single side or double side?

DR. FINDER: That is double-sided, triple-column.

MS. FISCHER: One thing you should know is that since they came out, we found mistakes. For example, what you will see in the equipment section is that some of the plus/minuses were left out. We have hand-written them in to your copies and the Federal Register will correct them.

DR. FINDER: As for future meetings, one thing that we have to keep in mind is the fact that we are going to be replacing about a third of the committee for the next meeting so we really can't set dates too well. What I would be hoping for is to be talking about a meeting in March or April of 1998.

Obviously, we will keep in touch with you about that. Some of the topics that we are considering putting on at that meeting would be states as certifiers. Another would be a look at the inspection process. Other areas that may pop up again depending on how things go are interventional mammography and digital mammography depending on what we hear from various groups in the meantime between

now and that meeting.

So, basically, what I would ask you to do is try and stay open for those months. You can leave that open, a month or two here, and be prepared to leave at any moment. But we obviously will be getting back to you. A lot of it is going to depend on what we can arrange with the new members when they come on, too.

So, chances are, you are going to be getting, just like you did for this meeting, a list of possible dates. We will ask for your opinions or your requests on when to have the meeting. We will try and accommodate those.

The other thing that you should be prepared to receive in the mail is we will be sending you transcripts, on disc. You don't want to receive the hard copy which is about this thick. So we will send that to you on disc and we will also be sending you a summary of the meeting. That will be on hard copy.

So just wait by your mailbox.

Does anybody have any questions?

MS. HEINLEIN: Our term doesn't really expire until the end of January, so does that mean we will get copies of this meeting, the transcripts from this meeting, then?

DR. FINDER: Yes; you will be getting copies of

the transcripts and the summary. In fact, all of you who will be rotating off will be still members of the committee until January 31.

MS. HEINLEIN: Also I would just like to say that, having been here from the beginning, many of us went through a lot of anxiety when we found out that Charlie Showalter was no longer going to be the Executive Secretary and that Charlie Finder was coming in because we sort of hung on Charlie Showalter for so many years. I would just to comment what a wonderful job you are doing, Dr. Finder, and that now everyone will hang on you. So don't leave for a lot of years.

DR. FINDER: Thank you very much and yes, you will be able to have a copy of this.

DR. SMITH: I also want to say I was worried when I heard Charlie was coming on. I want to say, actually, this being my last meeting in all likelihood, I have really enjoyed it. I think it has been a great meeting. And I want to say to the rest, I can see you are in very good hands with Dr. Monsees. It has been a really tightly and well-run meeting.

DR. MONSEES: Thank you. [Applause.]

DR. HOUN: On behalf of FDA, I do want to thank all the old-timers--we refer to you as the old-timers

because you are here to the bitter end--for helping us through the very critical beginning period of MQSA. Really, we have gotten excellent advice. Many of the program changes have occurred because of your advice so, really, thank you.

DR. MONSEES: Thank you. We are adjourned.

[Whereupon, at 2:40 p.m., the meeting was adjourned.]